Centers for Medicare & Medicaid Services

R & D Projects Database

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

PDF TRACKING FORM

Tracking Job Number	***106***	Printed: 05/01/2002
Document Title	Medicare Cataract Surgery Alternate Payment Demonstration: Final Evaluation Report	
Author	Leo Reardon, Marian Wrobel, Lois Ol	Document Date 16-Oct-97
Document Description:	Final Report	

Project Specifics

SR Number	94-130
Project Number	500-94-0038
Project Title	Monitoring and Evaluation of the Medicare Cataract Surgery Alternate Payment Demonstration
Awardee	Abt Associates
Project Officer	Mason, Cynthia
Principle Investigator	Reardon, Leo
Funding Level	496049
Start Date	08/05/1994
End Date	10/30/1997
Project Description:	This contract assisted HCFA in the monitoring and evaluation of a demonstration to assess the feasibility of an all-inclusive negotiated price concept for cataract surgery. The negotiated price covering physician, facility, and intraocular lens costs for

Initiated (CMS):	sgallowya	Date:	01-May-02	Accepted (IQ):		Date:	
Released (IQ):		Date:		Received (Sub):		Date:	
Finished (Sub):		Date:		QC'd (IQ):		Date:	
Returned (IQ):		Date:		pproved (CMS):		Date:	

NTIS # PB98-106214
HCFA Contract # 500-94-0038
94-130
94_130_01_TJN106...
PIC = 6295

Abt Associates Inc.

55 Wheeler Street
Cambridge, Massachusetts
02138-1168

617 492-7100 *telephone*
617 492-5219 *facsimile*

Hampden Square, Suite 500
4800 Montgomery Lane
Bethesda, Maryland
20814-5341

301 913-0500 *telephone*
301 652-3618 *facsimile*

640 North LaSalle Street
Suite 400
Chicago, Illinois
60610-3781

312 867-4000 *telephone*
312 867-4200 *facsimile*

Medicare Cataract Surgery Alternate Payment Demonstration: Final Evaluation Report

Contract No. HCFA 500-94-0038

October 10, 1997

Leo B. Reardon
Marian V. Wrobel, PhD
Lois M. Olinger
Turahn Dorsey

Prepared for
Health Care Financing Administration
7500 Security Boulevard
Baltimore. MD 21244-1850

Prepared by
Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

The report presents the findings from the final evaluation of the Medicare Cataract Surgery Alternate Payment Demonstration. The 3-year demonstration tested the concept of a single global Medicare payment for outpatient cataract procedures. The report contains a background narrative on the project, a description of the site selection process, analyses of the impact of the demonstration on participating providers, an assessment of the clinical impact of the demonstration, and a summary of lessons learned.

This project was funded under HCFA Contract No. 500-94-0038. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of HCFA. The contractor assumes responsibility for the accuracy and completeness of information contained in this report.

Table of Contents

Executive Summary and Organization of the Study iii

1.0 Background, Objectives and Design Features of the Demonstration 1
1.1 Background of the Demonstration 1
1.2 Objectives of the Demonstration 3
1.3 Demonstration Design 3
1.3.1 The Cataract Bundle 4
1.3.2 Other Major Features of the Cataract Bundle 7
1.4 Selection of Demonstration Locations 8

2.0 Selection of Demonstration Participants: The Procurement Process 15
2.1 Introduction 15
2.2 The Procurement Process 16
2.2.1 The Pre-Application Process 17
2.2.2 The Final Application Process 18
2.3 Description of Participating Provider Organizations 20

3.0 Impacts of the Demonstration on Participating Providers in the Start-Up and Operations Period 24
3.1 Introduction 24
3.2 Demonstration Start-Up and Operations 24
3.3 Cost Reduction Initiatives of Participating Providers 26
3.4 Efforts to Market the Demonstration 27
3.4.1 Marketing Efforts to Medicare Beneficiaries 27
3.4.2 Marketing to Optometrists and Other Physicians 28
3.4.3 Surgery Volumes of Participating Providers in the Demonstration 29
3.5 Bundle Prices and Savings Estimates 30

4.0 Clinical Impacts of the Demonstration 31
4.1 Introduction 31
4.2 Research Methodology 32
4.2.1 Issues for the Evaluation 32
4.2.2 Data Sources 34
4.3 Comparison of Baseline Patients to PORT 36
4.3.1 Methodology 36
4.3.2 Results 37
4.4 Comparison of Demonstration Patients to Baseline Patients 40
4.4.1 Methodology 40
4.4.2 Results 41
4.5 Summary of Findings from Analysis of Clinical Data 47

5.0 Summary and Conclusion: Lessons Learned from the Demonstration 83
5.1 Introduction 83
5.2 Lessons Learned from the Demonstration 83
5.3 Summary and Conclusion 87

Executive Summary

Introduction

Abt Associates Inc. has been under contract to the Health Care Financing Administration (HCFA) since 1989 to assist in the design, implementation, administration, and evaluation of a demonstration of an innovative payment approach, known as package payment or bundled pricing, for cataract surgical episodes in the Medicare program. Officially known as the Medicare Cataract Surgery Alternate Payment Demonstration, the project sought to employ market forces to select providers and negotiate discounted prices for a package or bundle of specified preoperative, operative and postoperative services associated with an episode of cataract surgery. The demonstration is authorized by Section 1875 (42 U.S.C. 139511) of Title XVIII of the Social Security Act, which instructs the Secretary to conduct studies and develop recommendations relative to "methods for encouraging the further development of efficient and economical forms of health care" for the aged and disabled. The design phase of the project was completed in Spring of 1991. Demonstration operations under the package payment prices actually began in April 1993 at four provider sites in three demonstration locations: Cleveland, OH; Dallas, TX; and Phoenix, AZ. The demonstration operated for three years and concluded in April 1996.

Objectives of the Demonstration

The primary objective of the demonstration was to assess the potential benefits of a negotiated package pricing arrangement for cataract removal with an intraocular lens (IOL) implant. By testing this alternate payment system, HCFA sought to:

- allow provider flexibility in managing the mix and type of services used;
- provide incentives to manage patient care so that cost efficiencies are realized and the procedure can be performed at a lower total cost;
- reduce Government involvement in the pricing of individual services and in the providers' decisionmaking;
- provide insight into appropriateness indicators and effective quality assurance and utilization review mechanisms for cataract surgery; and
- provide information regarding factors influencing providers' decisions to participate and beneficiaries' decisions to select designated providers under a demonstration that is completely voluntary (i.e., "exclusive providers" were not established and HCFA did not guarantee increased volume to providers participating in the demonstration; beneficiaries remained free to choose providers not participating in the demonstration and those providers continued to be paid under the Medicare fee-for-service system).

To test this approach, HCFA decided that the demonstration would be implemented in three geographic locations and would operate for a period of three years.

Demonstration Design

Throughout the design phase of the project in 1989-1991, HCFA and Abt Associates solicited input and advice from medical professionals and related industry groups. A technical advisory panel comprised of such representatives addressed a broad range of issues pertaining to the demonstration's design. The panel's constructive suggestions regarding services to be included in any payment package, outlier policy, utilization review techniques, beneficiary and provider incentives, and site selection criteria, were instrumental in formulating a viable demonstration design. In addition, HCFA and Abt Associates convened several workgroups of Government experts in an effort to construct a project design which addressed all potential concerns over this three-year period.

The Cataract Bundle

The negotiated package payment was based on defined set of services over the entire episode of the bundle. They included: 1) pre-operative services provided immediately prior to surgery; 2) surgical services on the day of surgery; and 3) post-operative services for 120 days after the day of surgery.

Pre-Operative Services. The pre-operative stage included all diagnostic tests (e.g., A-scan ultrasound, specular microscopy, fluorescein angiogram) and the pre-operative surgical evaluation(s) (including keratometry) performed immediately prior to surgery. The pre-operative surgical evaluation establishes the final clinical determination by the designated provider of the need for cataract surgery.

Surgical Services. All services performed on the *day of surgery* were included in the bundled price. A waiting period of at least 7 calendar days was required between the pre-operative visit at which the decision is made to proceed with surgery and the day of surgery. HCFA included this rule in the demonstration to allow beneficiaries a one-week period in which to reconsider their need for the operation. The rule was inserted in response to charges by some critics of the project in the ophthalmologic community that the demonstration would lead to increased rates of unnecessary surgery by so-called high volume "cataract mills."

Post-Operative Services. The post-operative stage extended for 120 days after the day of surgery and included all post-operative examinations (usually four) and the final refraction. If the physician determined that an acceptable final refraction could be obtained earlier than 120 days, the 120-day window was still applicable for any examinations related to the cataract surgery which might occur up to the 120th day.

The package price to be paid by Medicare did **not** include the cost of eyeglasses or drugs prescribed upon discharge for self-administration. Eyeglasses prescribed after cataract surgery with insertion of an intraocular lens remained a covered item under Medicare: but they were paid for separately because of the variety of settings and providers beneficiaries may select for this service.

Exclusions from the Demonstration

Cataract surgery cases that met any of the following conditions were excluded from the demonstration and continued to be paid under regular Medicare fee-for-service payment rules:

- cataract surgeries performed in an inpatient hospital setting;
- cataract surgeries in which an IOL is not inserted;
- cataract surgeries which qualify for an assistant surgeon according to PRO criteria;
- aborted surgeries (those surgeries in which the cataract is not removed).

Selection of Demonstration Locations

Because Metropolitan Statistical Areas (MSAs) resemble natural market areas for cataract surgery, HCFA decided to use these locations for the demonstration. The decision to use MSAs as the area for the demonstration resulted in a choice of over 150 metropolitan areas from which to choose the treatment and control sites. After reviewing volume, costs, ASC penetration and other variables across all these potential sites, HCFA initially selected Albany/Troy, NY, Cleveland, OH, and Dallas/Ft. Worth, TX, as the three sites for the demonstration. However, due to low response rates to the request for applications from providers in the Albany area, HCFA decided to drop Albany and replace it with Phoenix, AZ as the third demonstration site.

Selection of Demonstration Participants: The Procurement Process

Ophthalmologists Sue HCFA

From the time HCFA announced the project in 1989 it had been actively opposed by most organized segments of the ophthalmologic community. When it became apparent to these groups in 1991 that the project would move forward despite their opposition, a lawsuit was filed on May 1, 1991 in the United States District Court for the Northern District of Ohio Eastern Division by the national ophthalmologic medical society, the American Academy of Ophthalmology, and by the Cleveland Ophthalmological Society for declaratory and injunctive relief against the Secretary of the U.S. Department of Health and Human Services (DHHS) and the Administrator of HCFA.

The suit dragged on for over a year with both sides filing various motions and two other medical societies attempting to join the suit. The plaintiffs first filed a motion for preliminary injunction with a memorandum in support. The Court declined to rule on the preliminary injunction motion, waiting to address the plaintiffs' claims on summary judgment.

The complaint was concluded on June 10, 1992 when Senior Judge Alvin I. Krenelor issued his opinion and order granting DHHS' and HCFA's motion for summary judgment on all the counts of the complaint and overruling the plaintiffs' motion for partial summary judgment.

On July 10, 1992, the plaintiffs appealed the District Court decision to the U.S. District Court of Appeals for the Sixth Circuit. The appeal was argued on May 3, 1993 and the Appeals Court decided and filed its opinion on July 9, 1993, affirming the District Court's decision and order. Plaintiffs requested a rehearing before the Appeals Court which the Court denied on August 24, 1993.

Although DHHS and HCFA were ultimately successful in court, the suit generated additional negative publicity for the demonstration and may have further discouraged providers from participating in the project.

The Procurement Process

HCFA conducted a two-stage procurement process over the 1991-1992 period to solicit and evaluate applications from provider entities to participate in the demonstration. The two-stage process consisted of:

- Stage One — a Request for Pre-Applications from institutional (hospitals, ASCs) and professional (ophthalmologists) providers in the demonstration areas for expressions of interest and summaries of qualifications for participating in the demonstration;
- Stage Two — a Request for Final Applications, with detailed experience and qualification data and proposed package prices from the most qualified provider entities among the pre-applicants in each demonstration area.

The two-stage procurement process was intended to reduce the overall burden on providers in applying to participate in the demonstration. The simplified pre-application phase allowed providers to assess their interest in and capabilities for participating in the demonstration.

Results of the Pre-Application Process

HCFA mailed over 1,000 pre-application packages to providers in the four sites who had billed Medicare for cataract surgery services in the previous year. Across the four sites, only 38 applications were received, for a combined response rate of 3.7 percent. The number of applications received on a per site basis were: 3 in Albany/Troy; 20 in Dallas/Ft. Worth; 10 in Cleveland; and 5 in Phoenix. Of the 35 pre-applications received from providers in the final three demonstration areas, 29 were judged to meet demonstration criteria and to warrant an invitation to submit a final application.

Results of the Final Application Process

HCFA received a total of 21 final applications from the 29 providers invited to participate in this process. Of these, six provider organizations were selected as finalists for negotiations with HCFA. Of the six finalists, two providers withdrew from negotiations, and HCFA successfully negotiated final package prices and other terms and conditions of participation with the remaining four provider organizations.

Brief descriptive profiles of the four provider organizations selected by HCFA to participate in the demonstration appear below.

Cataract Eye Center of Cleveland, Inc. The lead provider entity for this organization, hereafter referred to as Cataract Eye, is a professional physician group practice corporation consisting of two ophthalmologists. Cataract Eye performed, on average, over 800 cataract surgery cases per year. It has four offices in the Cleveland area, with its main office located downtown in a medical office building adjacent to St. Vincent Charity Hospital and Health Center, which, until the last year of the

demonstration, was the sole facility where surgeries were performed for demonstration patients of this provider organization.

Medical Eye Associates, Inc., the lead provider entity for the other Cleveland participating provider organization, is a professional physician group practice corporation consisting, at the beginning of the demonstration, of four physician equal partners in the practice. Combined, the four physicians had performed about 270 cataract surgery procedures in 1990.

Included in its application were two local area hospitals: Deaconess Hospital of Cleveland and Parma Community General Hospital, and The Surgery Center, a free-standing ambulatory surgery facility.

Doctors Hospital of Dallas. The organizations included in this application were Doctors Hospital of Dallas, RHD Memorial Medical Center and Trinity Medical Center — all three facilities are located in the Dallas area and were owned and operated at that time by National Medical Enterprises, Inc., a national for-profit hospital chain. (The hospitals are now owned by Tenet Healthcare Corp., one of the largest national for-profit chains.) Of the three hospitals, Doctors Hospital had the highest volume of cataract surgeries and had the greatest number of participating ophthalmologists. Therefore, Doctors was selected by NME to serve as the lead hospital under the demonstration.

Seven ophthalmologists with staff privileges in these hospitals were included in the provider configuration. The seven cataract surgeons involved in the team combined to perform slightly under 1,300 cataract surgeries in Medicare in 1990.

Southwestern Eye Center, Ltd., is the lead and only provider entity for the participating provider in the Greater Phoenix area. Southwestern Eye is a physician professional corporation group practice with headquarters in Mesa and about eight other offices in the Phoenix/Mesa area as well as other parts of the state. Five ambulatory surgical centers (ASCs) are included in these locations, including the main ASC proposed for the demonstration located at the Dobson Road Facility in Mesa. With the exception of three contracted retina vitreous specialists, all physicians, certified registered nurse anesthetists and other staff proposed for the project were salaried employees of Southwestern Eye.

Impacts of the Demonstration on Participating Providers in the Start-Up and Operations Period

Coordination Among Affiliated Providers

Once the demonstration began, most lead provider entities reported typical administrative problems in establishing mechanisms within the configuration for 1) scheduling appointments with affiliated providers for particular services of the bundle, particularly in establishing dates for the surgical procedure; and 2) receipt of claims for specific services of the bundle from affiliated physicians and facilities in order to submit consolidated billings for the bundle to HCFA.

Some providers also required some time to work out procedures for completion of respective portions of patient checklists by affiliated providers during the four-month period covered by this document. By the time of our second wave of visits to these provider locations in the spring of 1994, most of these coordination problems had been resolved by the providers. However, all provider entities we

interviewed, whether lead or affiliated entities, but especially the former, reported that the simple task of collecting all relevant claims from all providers involved in the bundle episode and submitting these patient-specific claims in a complete package to HCFA was a more time-consuming and involved process than they had originally anticipated.

Reimbursement Difficulties

One problem that all provider organizations reported when the demonstration began and that persisted to a lesser degree throughout the project involved receiving payment from supplemental insurers for the beneficiary coinsurance and deductible amounts (i.e., the beneficiary liability portion of the bundle price). This was a major problem for all providers because such a high proportion (over 75 percent) of Medicare beneficiaries carry some type of Medicare supplementary insurance.

Their problems were twofold. First, it took about 60 days (after the bundle payment was received from HCFA) for providers to receive the EOMB from the FI in order to bill supplemental insurers. Thus, it was generally three months after surgery before providers could bill for Medicare copayment and deductible amounts. Second, the EOMB they received from Medicare for the bundle payment was unique; it looked and was formatted differently than a traditional EOMB and did not contain line item detail, including the usual procedure codes, of submitted, allowed, and paid amounts for individual services received by the beneficiary. The processing systems of most supplemental insurers had evolved over the years to rely on procedure code-specific line item detail on the EOMB (or its electronic media equivalent) to apply coverage and reimbursement screens to Medicare claims. In place of such detail, supplemental insurers were confronted with an EOMB that consolidated all services to one line item and charged a uniform copayment amount based on the bundle price HCFA negotiated with each provider. Naturally, most supplemental insurers, particularly at the beginning of the demonstration, refused to honor the EOMB.

However, as the project progressed and increasing numbers of Medigap insurers became familiar with the bundle EOMB, provider billing staff began to gradually devote less time and other resources to the supplemental claims reimbursement effort.

Cost Reduction Initiatives of Participating Providers

During our site visits in 1994 we asked participating providers if in fact they have taken any specific actions to reduce their costs for the cataracts episode after their first year experience with the demonstration. Officials and staff of three of the four participating providers cited anecdotal information that such actions had been taken. They are summarized below:

- One provider reported that at least one physician had made changes in his surgical technique with foldable lenses, smaller corneal incisions, and use of dissolving sutures. These changes had cut surgery time in half and permitted him to see patients less often after surgery. This had made the procedure itself more efficient and reduced the number of post-operative patient visits required in the typical case. There were also indications that one of the hospitals involved in this provider configuration had made changes in its method, agent, and staffing arrangements for anesthesia services associated with the surgery to reduce costs.

- Another provider standardized the entire package of materials used in the cataracts surgical procedure (medications, surgical instrument and supplies, the IOL, and pre-/post-operative medications) so it could purchase a tailored package of these materials at a discount price from one vendor for all its cataracts surgery patients, demonstration as well as non-demonstration patients.

- A third provider standardized the IOL it used for cataract surgeries. This provider also cited other, less tangible cost-efficiency benefits of its participation in the demonstration during our site visit. It noted the demonstration had prompted the practice to examine, for the first time, its costs per episode of cataract surgery at the individual surgeon level. This and other related moves placed the practice in a better position to compete for managed care business.

A key question about the initiatives discussed above is whether or not they can be listed as true impacts of the demonstration. Put another way, might they have taken place in the absence of the demonstration? The obvious answer is yes. In citing these initiatives we are in no way implying they are *direct impacts* of the demonstration. In fact, they are the exact type of actions one would expect any progressive provider to be initiating on an ongoing basis to reduce costs and improve the value of the service it delivers to its patients and payer clients. In relation to causality, the best one might say is perhaps the discount feature of the demonstration provided an additional reason, beyond those already operating in the healthcare marketplace, for participating providers to search for ways to reduce costs.

Marketing Efforts to Medicare Beneficiaries

Demonstration providers used a variety of methods and media to inform Medicare beneficiaries about their participation in the project. Most of these efforts were concentrated over the first year or less of the demonstration. After assessing the poor results of these early efforts, all providers had ceased expending any further effort or money to publicize the demonstration to area beneficiaries after the first year of operations.

The types of media used in these marketing efforts included the following:

- ***press releases*** — a number of providers used this device when the demonstration began to publicize their selection as a designated provider. One provider looked at the possibility of hiring a public relations firm to handle its campaign but learned that most firms were not interested in an account or campaign as small as that envisioned by the provider.

- ***direct mailings*** — two of the four providers sent information material to selected groups of senior citizens in their respective areas. The size of the mailings ranged between 2,000 at one provider to 37,500 at the other provider.

- ***newspaper advertisements*** — all providers placed advertisements in major (downtown) and suburban newspapers. In addition, at least one provider placed ads in publications aimed specifically at area seniors. One provider paid over $20,000 on its newspaper advertisements in one of the early calendar quarters of the demonstration.

- ***radio/TV spots*** — three demonstration providers paid for radio and TV spots (ranging between 30 to 60 seconds) to publicize their participation in the demonstration and the benefits of the project to Medicare patients. One provider paid for over 133 TV spots over the first few months of the demonstration. This provider also had a telemarketing department available to respond to its toll-free phone number publicized in these ads. Over the first 6 months of the demonstration, it received about 140 calls on this line as a result of these ads but these resulted in only 21 actual referrals to its surgeons for cataract surgery.

- ***other outreach efforts*** — most providers also had surgeons and staff speak at senior centers and health fairs to publicize their demonstration status.

As noted earlier, results of these marketing efforts were viewed as minimal and disappointing by all demonstration providers. Most pointed to the difficulty of explaining the complex administrative features of the demonstration to area seniors. They also had difficulties in explaining the financial benefits resulting from use of participating providers. Moreover, these benefits applied to only the estimated one quarter of all beneficiaries with no Medigap coverage and even for this group the savings offered to patients of most providers were too small to attract a high number of patients.

While it was difficult for beneficiaries to understand the complex administrative and financial aspects of the demonstration, those who did participate appreciated one feature of the demonstration; the reduced number of benefit and payment notices they received from Medicare as a result of the bundle payment. During our 1994 interviews, all demonstration providers reported that many beneficiaries had commented favorably about receiving only one explanation of Medicare benefits (EOMB) from Medicare in contrast to the multiple EOMBs they usually received under the conventional billing and payment systems. This again is an important impact finding of the demonstration.

We noted earlier that HCFA required demonstration providers to send them all marketing materials for prior review before they were used to publicize the demonstration. This is a fairly standard requirement which HCFA has imposed in most of its demonstrations of alternate payment methods over the years. While most providers understood the rationale for this pre-review and approval requirement, some thought this review was too legalistic. To quote one participating surgeon, "...when you advertise you can't make every ad sound like a legal statement — you lose your point."[1]

Surgery Volumes of Participating Providers in the Demonstration

Demonstration operations began in April 1993 at all participating providers except Medical Eye, which began operations in May of that year. Medical Eye also decided at the end of 1994 to cease participating in the project. The remaining three providers stayed in the project for its full three-year term and ceased demonstration operations in March/April 1996. The table below presents a summary, by provider and year, of the number of cataract surgery episodes billed by the providers to HCFA.

Volumes of episodes on a provider-specific basis varied considerably from a low of 413 at Medical Eye, to a high of over 1,800 episodes at Southwestern Eye, the highest volume provider. Southwestern

1 "InSight Focus: A Policy Issue Analysis from Insight Reports," Volume 10, No. 3, February 11, 1994.

Eye was also unique in that it was the only provider whose volumes increased from 1994 to 1995, the only operational period which included two full calendar years. During this period, Cataract Eye experienced a decline of 35.6 percent in its volume, while Doctors Hospital maintained fairly stable rates with a decline of only 3 episodes from 1994 to 1995.

To comment on the volume impact of the demonstration, we have to rely on anecdotal information supplied by the providers. On this issue only one provider, Doctors Hospital, reported an increase (about 10 percent) in volume during our site visits in 1994. However, the provider quickly qualified that by stating that it could not attribute this increase to the demonstration. All other providers reported no volume increases when interviewed in the 1994 site visits.

Number of Surgical Episodes Billed to HCFA Per Year

	Demonstration Provider Organizations			
Year/Provider	Cataract Eye	Medical Eye	Doctors Hospital	Southwestern Eye
1993	307	155	318	305
1994	367	258	457	605
1995	236	0	454	670
1996	13	0	122	299
Total	923	413	1,351	1,879

While most providers saw no increase in volume from the demonstration, or at least that could be attributed to the demonstration project, three providers reported their volume levels were stable between 1993 and 1994 in the face of what they perceived to be a diminishing market. Most thought their participation in the demonstration may have contributed to this stability. If their reflections are correct about both the demonstration's contribution and the general market, it would be an important impact.

Bundle Prices and Savings Estimates

HCFA negotiated relatively modest discounts, in the general range of 2 to 5 percent, compared to what it had paid demonstration providers under the fee-for-service system for the services included in the bundle episodes of the demonstration. The services included in the bundle episode are uniform across all provider sites and price adjustments are not allowed for differences in the ocular or general medical conditions of patients or for complications during or after surgery. During negotiations, HCFA persuaded providers to include the costs of treating complications in their price for the bundle. Across all provider sites, prices allowed by HCFA for bundle episodes (including any deductible and coinsurance amounts) averaged $2,250.01 in 1993, $2,213.54 in 1994 and $2,184.66 in 1995. The slight reductions in average prices each year reflect the fact that HCFA negotiated terms with providers that called for annual adjustments in bundle prices to reflect the changes in the Consumer Price Index (which would tend to increase prices) and legislatively mandated changes in the physician's fee

schedule for cataract procedures (which would tend to reduce prices). The net effect was slight reductions in the bundled prices across the sites over the three years of the demonstration.

Clinical Impacts of the Demonstration

This section explores the impact of the demonstration on clinical measures: the pre-operative characteristics of patients, the services they received, and the outcomes of care. It focuses on five issues: whether bundled payment caused providers 1) to enroll patients who were relatively lower risk, 2) to reduce the level of services provided to their patients, 3) to provide services more efficiently, 4) to alter the timing of services, and 5) whether the demonstration had any impact on the measurable outcomes of care, both complication rates and visual acuity.

The section uses comparisons of clinical data collected before and during the demonstration to draw inferences about its effects. The clinical data were collected via patient checklists described in more detail in Section 4.0 of this report.

Summary of Findings from Analysis of Clinical Data

Our main findings relative to the impact of the demonstration on clinical measures are:

- At baseline, patients of demonstration providers were fairly typical in terms of clinical measures.
- During the demonstration, one provider's patients exhibited more favorable pre-operative characteristics than had been the case at baseline; this could have been the result of risk selection or of biases in the data. The other two providers patients exhibited roughly similar pre-operative characteristics.
- No provider curtailed services during the demonstration.
- Two providers increased the percentage of their IOLs that came from their leading manufacturer between baseline and demonstration suggesting an increase in the efficiency of service provision.
- All providers decreased the percentage of their patients that received nd:YAG capsulotomies within 120 days of surgery. We hypothesize that this represented delaying (not eliminating) YAG in order to receive additional reimbursement for the procedure. However, as noted above, data limitations did not permit us to test this hypothesis.
- No change in clinical outcomes could be attributed to the demonstration.

Summary and Conclusion

Despite its modest savings impact, the demonstration was remarkably successful in meeting most of its original objectives. A brief summary of the demonstration's performance relative to each of these objectives follows.

Provider Flexibility in Managing Bundle Services. On this objective the project could be judged a reasonable success. Although the demonstration imposed demanding quality standards in its provider selection criteria, once providers satisfied these criteria and became participating providers, they had complete freedom to decide the type and amount of services to provide to demonstration patients, and who within the provider organization should provide those services.

Incentives for Cost Effectiveness. There is ample anecdotal evidence that the demonstration was successful in meeting this objective within most provider organizations. These cost reduction efforts included changes made by surgeons in the techniques and time required to perform the surgery and actions to standardize the IOLs and other supplies and materials used in the episode to reduce costs. In addition, the demonstration prompted one provider to perform a more comprehensive evaluation of all cost inputs to the episode.

Reduced Government Involvement In Pricing Bundle Services. This is not an easy objective to evaluate, mainly due to the design and selection criteria of the demonstration. On one hand, one could say that through the provider application and negotiation process the Government was intimately involved in all aspects of how applicants proposed to price and pay for all components of the bundle. On the other hand, once demonstration operations began, Government activities related to pricing were greatly reduced and limited to simple verification and payment of the global fee negotiated with each participation provider organization. Thus, on this measure also, the demonstration can be judged a reasonable success.

Provide Insight into Appropriateness Indicators, Quality Assurance and Utilization Review Mechanisms. On this multi-faceted objective the demonstration would have to be considered a partial success. As noted earlier, circumstances prevented us from performing the beneficiary survey which was to be an essential tool in developing the appropriateness indicators for cataract surgery. On this factor at least, the project did not meet its objective. On the quality control and utilization review components of this objective, the demonstration could be termed successful, as indicated by the unchanged outcomes of demonstration patients reported in Section 4.0.

Provide Information Regarding Factors Influencing Providers' Decisions to Participate and Beneficiaries' Decisions to Select Demonstration Providers. Here again, the project has to be judged a partial success. On the provider level, the project produced valuable new insights on the strengths and weaknesses of particular incentives in encouraging providers to participate in a voluntary and non-exclusive demonstration. However, in general, the project did not shed much light on what factors influenced decisions by beneficiaries to select participating providers. Of course, one reason this objective was not fulfilled was because the beneficiary survey could not be performed. Failure to meet this objective was not due to any intrinsic weakness in the overall design of the project. Nevertheless, in general, we would have to say the entire objective was only partially achieved.

Taking into account the demonstration's performance across all of these objectives, we think the overall conclusion is that the demonstration was a success. The valuable experience and lessons learned from this project have and will be used by HCFA to revise the design features of bundled payment programs and to apply these new approaches to future studies of this payment mechanism.

Organization of the Study

This report represents a much less comprehensive evaluation of the impacts of the demonstration than originally planned by HCFA and Abt Associates as detailed in the *Evaluation Design Report* of May 29, 1992. In that report, Abt Associates proposed to use Medicare claims history data for the 1992-1995 period to perform an extensive econometric analysis of the impacts of the demonstration on the cost and volume of cataract surgery services and on the treatment patterns of the surgical episode in demonstration and control areas. Pre/post, contemporaneous, and double-difference comparisons were to be used to assess the impacts of the demonstration on these key measures. In addition, we also planned to survey a sample of cataract surgery patients at treatment sites during the final year of the demonstration to assess their visual acuity, functional status, and satisfaction with the surgical experience. Data from the patient survey, along with clinical and service utilization data from the Cataract Surgery Patient Checklists (see Appendix A for a copy of the Checklists), were also to be used to develop and validate clinical indicators to be used in a synthesis of practice guidelines for the appropriateness of cataract surgery.

Since that report was prepared, a number of unforeseen delays have occurred which precluded the use of these major data sources in the evaluation. The net result is a dramatically scaled-back evaluation from what was originally proposed in 1992. Of the five major data sources originally proposed at that time — 1) provider applications; 2) clinical checklist data; 3) site monitoring/case study data; 4) Medicare claims history; and 5) beneficiary survey data — only the first three can be used in this report. With these limitations in mind, we must rely on information obtained from the demonstration providers themselves, in their applications (to HCFA) to participate in the demonstration, and in the two rounds of case study interviews, along with readily available published data, to assess the impacts of the demonstration on the cost and volume of cataract surgery. The evaluation of service utilization and quality of care impacts will rely on data from the patient clinical checklists collected during the demonstration and during a baseline period. This evaluation also puts the demonstration into perspective using data from an earlier research project, the Patient Outcome Research Team (PORT) project on cataract surgery conducted in the early 1990s by researchers at the Johns Hopkins University. Other more general impacts, such as those on the administrative and financial systems of providers and on beneficiary reactions to the simplified billing and lower copayments of the demonstration will also rely on information obtained from our case study interview activities.

This report is organized as follows. Section 1.0 reviews the purpose and objectives of the demonstration and describes its major design features. Section 2.0 reviews the procurement phase of the demonstration and provides descriptive summaries of the demonstration provider organizations that were selected from that process. Section 3.0 reviews the operational phase of the demonstration. Here we discuss the limited findings available on the cost and volume impacts of the demonstration. Also included in this section are some major findings from our interviews with demonstration provider entities, including startup and operational problems and efforts to reduce the costs of services and products included in the cataract surgical episode. Section 4.0 discusses the findings from analyses of

the patient checklists, including those related to service utilization patterns, visual acuity, and quality of care measures. Where relevant, findings from the demonstration are compared to those from an earlier research effort, the PORT Project at Johns Hopkins University noted above. Section 5.0 presents a summary of the major lessons learned from the demonstration and an assessment of the overall success of the demonstration in relation to its original objectives.

1.0 Background, Objectives and Design Features of the Demonstration

1.1 Background of the Demonstration

To understand the factors which influenced HCFA's decision to mount the demonstration in Medicare, one must go back to the late 1980s. By the late 1980s, growth rates of Medicare expenditures for hospital services had been slowed considerably by the introduction of the prospective payment system (PPS) for inpatient services earlier in the decade. While lower growth rates in the inpatient setting were one of the intended effects of PPS, it, along with technological advances, led to the shift of a number of services, including many surgical procedures, from the inpatient to the outpatient setting where there were no corresponding prospective controls on expenditure outlays. Over this period, growth rates for Medicare Part B services continued to climb at double-digit levels. Annual rates of increase in Part B expenditures averaged about 20 percent between 1984 and 1986. An examination of the factors that contributed to these growth rates called attention to those procedures that displayed the most costs and greatest volume in the Part B program. A 1988 Physician Payment Review Commission Report to Congress found cataract surgery to be the surgical procedure most frequently performed on Medicare beneficiaries and, consequently, the single most costly procedure in the Part B program.

During the period 1984–1987, performance of cataract procedures increased at an annual rate of about 20 percent, in part because of technological advancements in both the surgical technique and the IOL implant and the shift in surgical setting from inpatient to outpatient locations. While the volume of cataract surgeries began to stabilize after 1987, by 1990 total Medicare reimbursements for cataract surgery exceeded $3 billion for approximately one million procedures. In 1989, the GAO reported that the per-case cost for cataract surgery had not significantly decreased to reflect the technological improvements and streamlined procedures introduced over these years but rather had stabilized because of regulatory intervention and Congressional mandates.[2] These included regulations introduced by HCFA in 1987 to reduce payment levels for intraocular lenses (IOLs) and provisions in the Omnibus Budget Reconciliation Acts (OBRAs) of 1986 and 1987 to reduce the amounts Medicare would pay to facilities and physicians for cataract procedures in the outpatient setting. These actions produced results: average Medicare allowed charges for primary surgeons of cataract surgery decreased by 25 percent between 1986 and 1991.[3]

Pressure was also building from other sources to do something about these spending levels for Part B in general and high volume surgical procedures in particular. The *Detroit News and Free Press* ran an article on high-volume surgeons, or, to use its term, "big cutters," including those for cataract surgery, who received millions of dollars a year in payments from Medicare.[4] This rather sensational article

---

2 "Medicare: GAO Views on the Payment System for Outpatient Cataract Surgery." Testimony by M. Zimmerman, Director, Medicare and Medicaid Issues before U.S. House of Representatives, Committee on Ways and Means; April 10, 1989.

3 Steinberg, Earl P. et al. The Content and Cost of Cataract Surgery, *Arch Ophthalmol* 1993, 111:1041-49.

4 *Detroit News and Free Press*, Sunday, January 28, 1990.

was followed by a Congressional inquiry into "buccaneer surgeons," again based on aggregate annual Medicare payment levels to high-volume surgeons.

All these factors led policymakers to devote considerable resources to develop various alternatives to controlling the apparently ever-increasing expenditures for physician services in Medicare's Part B program. Greatest attention over this period was focused on developing a proposed fee schedule based on a "resource-based" relative value scale by researchers at the Harvard School of Public Health under contract to HCFA. This fee schedule, which was subsequently implemented in Part B in 1992, would set fees for almost all physician services, including surgical procedures, based on the workload entailed in each service as measured by panels of physicians.

Meanwhile, HCFA was also exploring other options to control growth rates in expenditures for physician services, including those focused on specific surgical services. One was a model emerging in the private, primarily managed care sector, in which health plans contracted with selective providers for an entire category or episode of services at discounted rates for all or a portion of the plan's enrollees. In exchange for lower payment levels, providers were guaranteed almost exclusive access to all, or a defined portion, of the plan's patients needing the services. Although most of these earlier approaches to selective contracting involved broad categories of high-cost services, e.g., cardiac care services, some were centered on high-cost/high-volume surgical procedures such as organ replacement procedures, and involved the payment of a fixed fee (usually negotiated) for the provision (and management) of all services related to the surgery, including diagnostic and other services prior to surgery, and a defined set of institutional and ambulatory services after surgery. These arrangements came to be known in the industry as "package payment" or "bundled payment" programs.

By the late 1980s, HCFA was ready to move forward with plans to test a variant of those bundled payment programs for surgical services in Medicare. The first surgical procedure it selected for its test was coronary artery bypass graft (CABG) surgery. The CABG bundled payment demonstration began operations in May/June 1991 when four hospitals in different cities started receiving global payment rates from HCFA for all Part A and Part B inpatient services associated with an episode of bypass surgery. The second surgical procedure selected by HCFA was cataract removal surgery with the insertion of an interocular lens (IOL). Both procedures were selected primarily because of their overall aggregate expenditure levels in Medicare. Cataract surgery was viewed as a particularly good procedure on which to apply such a demonstration for a number of reasons. Since cataract surgery is generally done in an outpatient setting with a limited number of ancillary services, it would be relatively easy to define an appropriate package of services to include in the episode bundle for the demonstration. At the same time, the potential benefits from reducing costs for cataract surgery were large because of its high volume (over 1 million procedures annually) in the Medicare population. According to work by Mitchell of Health Economics Research, growth in cataract surgery accounted for 7 percent of the rise in Part B spending between 1983 and 1986 and 25 percent of the growth in surgical spending. This increase in volume was at least partially attributable to changes in technology that simplified the procedure (and made it possible to perform on an outpatient basis) so that it became appropriate for less severely impaired and larger numbers of patients.

1.2 Objectives of the Demonstration

The primary objective of the demonstration was to assess the potential benefits of a negotiated package pricing arrangement for cataract removal with an intraocular lens (IOL) implant.[5] By testing this alternate payment system, HCFA sought to:

- allow provider flexibility in managing the mix and type of services used;
- provide incentives to manage patient care so that cost efficiencies are realized and the procedure can be performed at a lower total cost;
- reduce Government involvement in the pricing of individual services and in the providers' decisionmaking;
- provide insight into appropriateness indicators and effective quality assurance and utilization review mechanisms for cataract surgery; and
- provide information regarding factors influencing providers' decisions to participate and beneficiaries' decisions to select designated providers under a demonstration that is completely voluntary (i.e., "exclusive providers" were not established and HCFA did not guarantee increased volume to providers participating in the demonstration; beneficiaries remained free to choose providers not participating in the demonstration and those providers continued to be paid under the Medicare fee-for-service system).

To test this approach, HCFA decided that the demonstration would be implemented in three geographic locations and would operate for a period of three years.

1.3 Demonstration Design

Throughout the design phase of the project in 1989-1991, HCFA and Abt Associates solicited input and advice from medical professionals and related industry groups.[6] A technical advisory panel comprised of such representatives addressed a broad range of issues pertaining to the demonstration's design. The panel's constructive suggestions regarding services to be included in any payment package, outlier policy, utilization review techniques, beneficiary and provider incentives, and site selection criteria, were instrumental in formulating a viable demonstration design. In addition, HCFA and Abt Associates convened several workgroups of Government experts in an effort to construct a project design which addressed all potential concerns over this three-year period.

---

5 The specific cataract procedures eligible for bundled payment are defined by CPT-4 procedure codes 66983 (Intracapsular cataract extraction, insert IOL, one stage) and 66984 (Extracapsular cataract removal, insert IOL, one stage, manual/phacoemulsification technique). CPT-4 stands for Current Procedural Terminology, Fourth Edition, a coding and terminology system developed, maintained, and copyrighted by the American Medical Association.

6 American Academy of Ophthalmology (AAO), American Society of Cataract and Refractive Surgery (ASCRS), Outpatient Ophthalmic Surgery Society (OOSS), Society of Geriatric Ophthalmology (SGO), Society for Ambulatory Care Professionals, American Hospital Association (AHA), American Optometric Association (AOA), and the American Society of Ophthalmic Administrators (ASOA).

1.3.1 The Cataract Bundle

The episode of care for a typical cataract patient for purposes of the demonstration was divided into three components:

- **Pre-demonstration** services provided prior to demonstration covered services and paid for under the usual Medicare fee-for-service payment system;
- **Demonstration** services provided and paid for under the bundled payment;
- **Post-demonstration** services provided after 120 days from the date of surgery and paid for under the usual Medicare fee-for-service payment system.

Each component includes distinct services for which payment would be based on either usual Medicare fee-for-service rates or on a negotiated bundled rate paid under the demonstration waiver. Each of these components is described in more detail below. Exhibit 1.1 presents a schematic illustration of these episode components.

Pre-Demonstration

All services provided prior to the ophthalmological diagnostic tests and exam required for surgery were paid under the regular Medicare fee-for-service reimbursement system. Services covered under fee-for-service reimbursement included ophthalmologic examinations that determine the presence of cataracts and establish the need for surgery and the general physical examination and the medical release necessary for surgery.

These services were not included in the demonstration package pricing arrangement because the initial medical examination(s) which identifies the presence of a cataract may occur over lengthy, variable periods of time, and because those services and the preoperative comprehensive physical examination may involve a variety of physicians (including the beneficiary's primary care physician) who are not directly or regularly affiliated with the demonstration providers.

Demonstration

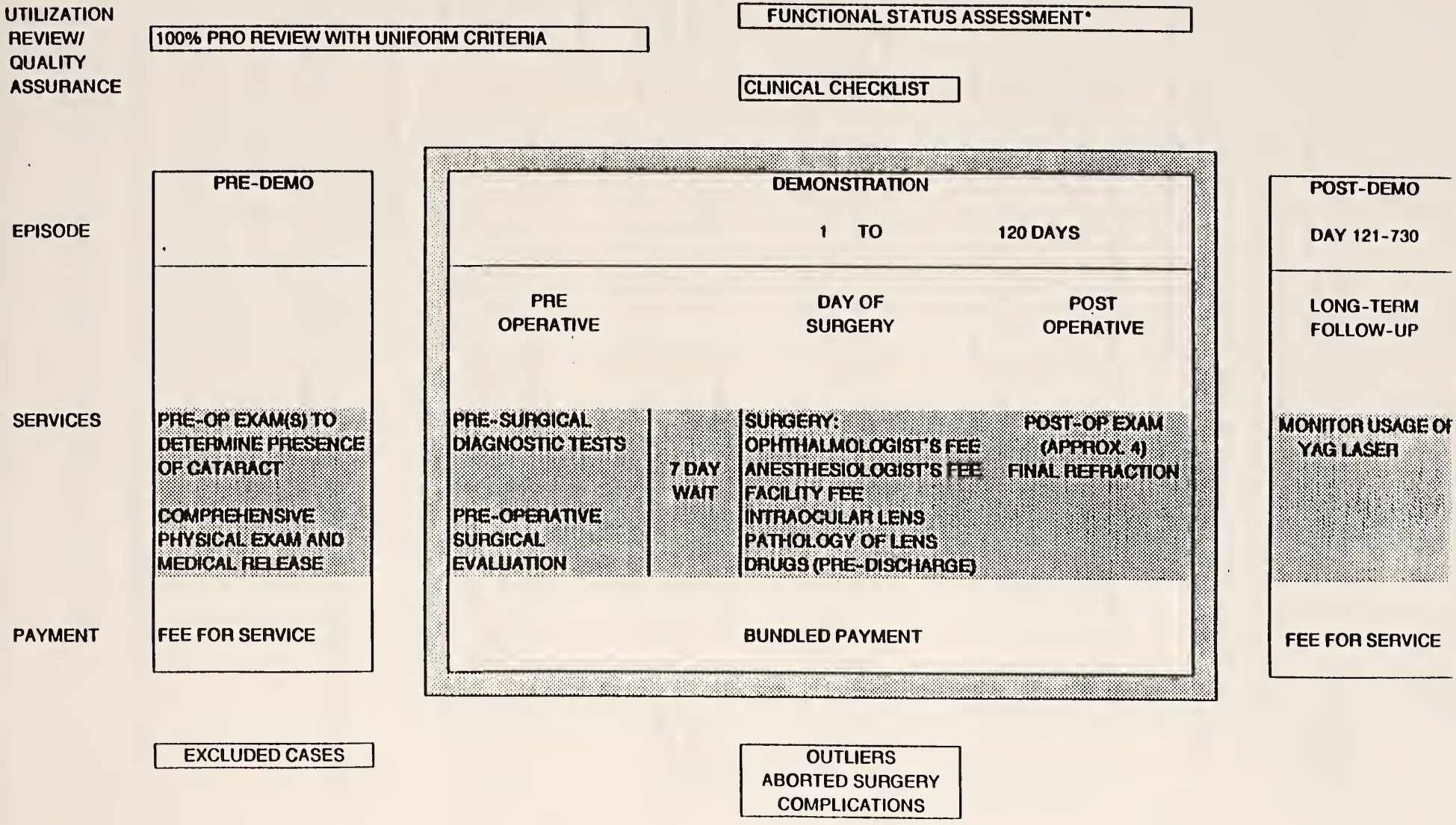
The negotiated bundled payment was based on defined set of services over the entire episode of the bundle. They included: 1) pre-operative services provided immediately prior to surgery; 2) surgical services on the day of surgery; and 3) post-operative services for 120 days after the day of surgery.

Pre-Operative Services. The pre-operative stage included all diagnostic tests (e.g., A-scan ultrasound, specular microscopy, fluorescein angiogram) and the pre-operative surgical evaluation(s) (including keratometry) performed immediately prior to surgery. The pre-operative surgical evaluation establishes the final clinical determination by the designated provider of the need for cataract surgery.

These pre-surgical assessments may also identify beneficiaries whose surgeries should be excluded from the package pricing arrangement due to complex ocular or medical conditions; pre-operative tests and surgical evaluations for those excluded beneficiaries were paid under the regular Medicare fee-for-service system.

Exhibit 1.1

MEDICARE CATARACT SURGERY ALTERNATE PAYMENT DEMONSTRATION
SCHEMATIC MODEL OF PAYMENT



*for a sample of beneficiaries

Surgical Services. All services performed on the *day of surgery* were included in the bundled price. A waiting period of at least 7 calendar days was required between the pre-operative visit at which the decision is made to proceed with surgery and the day of surgery. HCFA included this rule in the demonstration to allow beneficiaries a one-week period in which to reconsider their need for the operation. The rule was inserted in response to charges by some critics of the project in the ophthalmologic community that the demonstration would lead to increased rates of unnecessary surgery by so-called high volume "cataract mills."

Although the surgery services covered by the bundled price included the pathology of the extracted lens, this procedure is not generally considered to be necessary, and no additional fee was paid by Medicare to demonstration providers for this service. It was included in the bundle because it may be required by the facility in which the surgery is performed. However, providers who did require this procedure and hence included its cost in their overall package price may have been at a disadvantage during the selection process relative to other providers, since it would tend to increase their price for the bundle.

Post-Operative Services. The post-operative stage extended for 120 days after the day of surgery and included all post-operative examinations (usually four) and the final refraction. If the physician determined that an acceptable final refraction could be obtained earlier than 120 days, the 120-day window was still applicable for any examinations related to the cataract surgery which might occur up to the 120th day.

The package price to be paid by Medicare did **not** include the cost of eyeglasses or drugs prescribed upon discharge for self-administration. Eyeglasses prescribed after cataract surgery with insertion of an intraocular lens remained a covered item under Medicare: but they were paid for separately because of the variety of settings and providers beneficiaries may select for this service.

Post-Demonstration

This phase encompassed HCFA's long-term monitoring and follow-up of demonstration cases. All services provided after 120 days from the day of surgery were reimbursed according to Medicare's usual fee-for-service payment rates. However, patients were to be monitored for complications as well as occurrence of opacification resulting in the need for YAG laser surgery during this period.

Exclusions from the Demonstration

Cataract surgery cases that met any of the following conditions were excluded from the demonstration and continued to be paid under regular Medicare fee-for-service payment rules:

- cataract surgeries performed in an inpatient hospital setting;
- cataract surgeries in which an IOL is not inserted;
- cataract surgeries which qualify for an assistant surgeon according to PRO criteria;
- aborted surgeries (those surgeries in which the cataract is not removed).

1.3.2 Other Major Features of the Cataract Bundle

Definition of a Provider and Other Related Design Elements

There were few restrictions on the types of organizations that could be considered for selection in the demonstration. However, there were basic conditions for participation that all provider applicants had to satisfy. They were:

- Each designated provider agreed to receive a single negotiated global payment for all demonstration-covered services related to cataract surgery. This global payment represented payment in full;

- All designated providers were required to accept assignment, i.e., designated providers could not balance bill Medicare beneficiaries for amounts other than Medicare deductible and coinsurance amounts for demonstration-covered services;

- The negotiated global fee for the cataract episode had to represent a discount from the amount Medicare would otherwise pay for the sum of itemized services included in the bundle;

- All facilities participating in the demonstration had to be Medicare-certified;

- All facilities were required to have established capabilities for effectively handling medical emergencies; and

- Lead and other affiliated providers were required to cooperate with HCFA and its contractor in providing data for demonstration monitoring and evaluation.

Aside from the conditions listed above, HCFA imposed few additional restrictions on providers participating in the demonstration other than those that applied to the regular Medicare program. One exception, however, was HCFA's stipulation that it review and approve all marketing materials used by demonstration providers to publicize their designation as "Medicare Designated Cataract Surgery Providers." HCFA had been including this provision in most of its cost containment experiments to prevent abuses in marketing programs that had occurred in some of its earlier demonstrations. Although providers knew of this provision prior to submitting their applications, many complained later in the project that HCFA was too restrictive in what it allowed providers to say in these materials.

One issue explored in detail in the design phase of the demonstration was whether participating providers could waive collection of a portion or all of beneficiary deductible and coinsurance amounts as an incentive for beneficiaries to select participating providers. Most applicants proposed to waive collection of those amounts *only* for beneficiaries without supplemental insurance to pay those costs. Providers were not willing to forego payment of these amounts for *all* demonstration beneficiaries. HCFA ruled against these selective waivers on the grounds that it would disadvantage supplementary insurers (and their beneficiary subscribers who often paid the premiums) who will still be required to pay these amounts. Thus, the demonstration design contained no direct financial incentives, other than the reduced copayment amounts that were a by-product of the discounted prices for the bundle, for beneficiaries to choose demonstration providers. HCFA could not channel beneficiaries to those

providers through an exclusive contracting arrangement because it was precluded from doing so by Congressional proscription. What the government was offering then was the imprimatur of being a "Medicare Designated Cataract Surgery Provider" for providers to use carefully (with HCFA oversight) in their efforts to attract more patients to their practices. Each cataract surgery outpatient facility and surgeon had to assess the value of this designation, along with other related factors, in deciding whether to apply to participate in the demonstration.

1.4 Selection of Demonstration Locations

As a pilot study, HCFA had decided early in the project that the demonstration would be restricted to a limited number of geographic areas and that selection of those areas should be based on a number of factors reflecting various market conditions for cataract surgery. In addition, since a rather extensive evaluation of the demonstration was planned at the time, selection of control areas to which the demonstration areas could be compared would also be an important component of the selection process. As the design process got underway, three broad goals were established to guide the selection process. Areas selected as treatment or control sites had to be:

- Nationally representative;
- Comparable; and
- Contain sufficient sample sizes to generate statistically valid measures of demonstration effects.

Before establishing a meaningful set of selection criteria, the concept of an 'area' had to be carefully defined. The variation in coding practices and claims processing procedures employed by the different carriers required that comparison areas be selected from the same carrier territory as demonstration areas, and that they meet all requirements placed on demonstration areas. For example, if outcomes in comparison sites evolved under a different set of general carrier procedures than those in demonstration sites, the impact of carrier differences might be inappropriately interpreted as an effect of the demonstration. Selecting demonstration and comparison providers from the same carrier territories would ensure that those carrier rules not changed under the demonstration were applied uniformly in both demonstration and control areas.

In order to test the impact of bundling all services associated with cataract surgery, the areas in which the demonstration would be tested should resemble natural market areas for cataract surgery. Metropolitan Statistical Areas (MSAs) generally define reasonable economic markets in urban areas. Rural sections of the country, however, are not likely to be represented in the demonstration under this definition, except to the extent that MSA boundaries stretch into rural areas. Other options include defining an 'area' to be an entire state, or counties within a state. However, many states are not homogeneous throughout except in relation to the regulations they enforce. Counties, on the other hand, are too small and many generate border crossing (e.g., beneficiaries in control areas using providers in demonstration areas). As a result, it was decided to select demonstration and control areas according to MSA boundaries. However, to the extent that state regulations and other state-level factors affect the market conditions within a MSA, state characteristics were also considered in selecting MSAs as demonstration and control areas.

As mentioned above, using the MSA as a boundary to select demonstration and control areas excludes the possibility of testing the effect on bundling services for cataract surgery in rural areas. However, this is only important if practice patterns vary significantly between urban and rural settings. The Technical Advisory Panel (TEP) established to assist HCFA and Abt Associates in the design process felt that it would be unwise to select a rural location as one of the geographic areas. They felt that neither the number of ophthalmologists practicing in rural areas nor the number of cataract surgeries performed in rural areas was large enough to provide sufficient data from a demonstration. In addition, generalizations from a rural area would be impossible. Given the limited scope of the demonstration, it seemed that more information would be gained from concentrating on urban areas, which is consistent with using MSA boundaries to define the geographic area in which to test the demonstration. Thus, selection criteria needed to be established for the geographic areas (e.g., state and MSA) within carrier territories for inclusion in the demonstration.

Geographic Area Criteria

The following four factors were established to guide the selection of MSAs within states:

Charges: To maximize the potential savings to Medicare, states with charges for cataract surgery that are higher than the national average, after adjusting for cost-of-living variation, should be considered.

Volume: To evaluate demonstration effects, areas must have a sufficient volume of cataract surgeries. Absent volume data at the MSA level, it was decided that a minimum of 10,000 cataract surgeries annually at the state level was appropriate.[7]

Beneficiaries and Ophthalmologists: In order for normal market conditions to exist, areas with at least average percentages of Medicare beneficiaries and ophthalmologists should be considered.

In addition, MSAs also had to meet two other conditions:

- Demonstration areas should be geographically distinct from comparison areas so as not to contaminate the evaluation design (e.g., border crossing effects).

- Demonstration and comparison MSAs should be as similar as possible with respect to demographic characteristics and market conditions.

The charge, demographic, and volume data at the state level are shown in Exhibit 1.2 for 1987.[8]

---

7 Given that about 1 million cataract surgeries were performed in 1987, 10,000 surgeries represents about one percent of the national volume of surgeries.

8 The charge and volume data, shown in Exhibit 1.2, are derived from BMAD I (Procedure File, 1987) and thus do not map exactly to states or MSAs. Carrier territories, in most cases, approximate state boundaries. Similarly, in most cases, Medicare pricing localities approximate MSA boundaries. Demographic data (e.g., number of Medicare beneficiaries and ophthalmologists) are available from the County and State Area file, Prospective Payment Analytic Support Studies, Abt Associates Inc., 1988.

Exhibit 1.2
Volume and Allowed Charges for Cataract Surgery by State
1987

State	Number Cataract Surgeries Performed Annually (A)	Percent Cataract Surgeries With Assistant Surgeon (A)	Average Allowed Charges			Percent of Cataract Surgeries Performed in:			
			Primary Surgeon (A)	Anesthesiologist (B)	Assistant Surgeon (A)	Inpatient (A)	Hospital OPD (A)	ASC (A)	Physician's Office (A)
Alabama	16,614	•	$1,361	$139	$237	1	77	N/A	2
Alaska	381	32	$2,347	N/A	$446	6	93	N/A	2
Arizona	16,856	7	$1,906	$232	$387	•	43	54	2
Arkansas	8,920	1	$1,353	$131	$270	2	77	2	•
California (E)	78,478	15	$1,934	$204	$390	3	82	13	2
Colorado	9,256	14	$1,332	$173	$262	2	18	79	1
Connecticut	9,581	5	$1,533	$171	$338	21	58	11	9
Delaware	1,873	N/A	$1,325	$112	N/A	2	48	46	4
Washington D.C.	6,750	6	$2,329	$196	$521	6	19	66	8
Florida	72,071	1	$1,542	$193	$370	2	68	24	6
Georgia	20,616	1	$1,617	$183	$302	2	16	79	3
Hawaii	2,298	•	$1,752	$259	$265	4	47	43	1
Idaho	2,058	3	$1,308	$137	$264	9	72	14	5
Illinois	38,877	4	$1,738	$187	$382	4	28	66	1
Indiana	20,790	1	$1,450	$152	$94	4	77	18	1
Iowa	9,680	•	$1,455	$128	$218	9	88	N/A	2
Kansas	6,382	•	$1,358	$145	$269	4	84	N/A	3
Kentucky	10,921	2	$1,571	$127	$328	3	75	16	6
Louisiana	20,443	2	$1,721	$172	$332	3	77	17	2
Maine	3,644	•	$1,377	$137	$266	18	72	6	3
Maryland	8,388	9	$1,600	$88	$328	7	91	1	1
Massachusetts	20,053	4	$1,596	$167	$360	14	69	14	3
Michigan	34,619	2	$1,914	$145	$418	1	81	17	1
Minnesota (F)	8,290	3	$1,325	$129	$332	10	75	12	2
Mississippi	11,387	•	$1,352	$269	$545	2	68	27	3
Missouri (G)	23,491	1	$1,470	$157	$307	3	79	12	•
Montana	623	1	$1,479	$212	$320	6	92	N/A	2
Nebraska	5,643	•	$1,300	$145	$232	9	89	N/A	2
Nevada	3,010	10	$2,028	$247	$392	•	48	48	3
New Hampshire	2,810	10	$1,433	$147	$312	8	71	18	3
New Jersey	24,353	27	$1,521	$194	$347	11	33	53	4
New Mexico	3,469	6	$1,984	$195	$388	4	85	1	10
New York (H)	44,117	30	$1,940	$200	$446	33	37	N/A	4
North Carolina	25,897	•	$1,579	$117	$309	1	6	89	3
North Dakota	3,790	•	$1,480	$172	$302	2	93	•	5
Ohio	36,075	•	$1,708	$183	$366	9	79	9	2
Oklahoma	14,936	1	$1,382	N/A	$260	2	96	•	1
Oregon	9,992	18	$1,664	N/A	$289	2	87	9	2
Pennsylvania	44,419	2	$1,640	$160	$331	11	15	66	5
Rhode Island	4,134	2	$1,468	$119	$294	7	84	N/A	9
South Carolina	9,310	•	$1,434	$143	$426	4	90	N/A	5
South Dakota	2,901	•	$1,760	$172	$302	3	58	37	1
Tennessee	18,508	1	$1,433	$35	$287	5	91	2	2
Texas	66,573	N/A	$1,874	$182	N/A	1	5	90	3
Utah	991	1	$1,328	$175	$261	1	38	N/A	61
Vermont	1,759	27	$1,449	$147	$312	8	75	N/A	18
Virginia	13,187	1	$1,312	$133	$272	4	86	1	8
Washington	15,714	2	$1,525	$166	$324	9	23	65	2
West Virginia	7,315	N/A	$1,631	$137	N/A	7	87	4	2
Wisconsin	13,377	2	$1,338	$142	$277	5	37	55	3
Wyoming	275	5	$1,185	$178	$239	32	68	N/A	N/A
Total U.S.	835,895	5	$1,655	$159	$384	6.09	55.93	37.01	3.22

For references see Endnotes for Exhibits, Appendix D

• less than 1%
N/A Not available

In addition to the above volume and cost statistics, the design team also felt it was useful to select geographic areas in carrier territories with varying characteristics relative to:

- Regional variation (e.g., northeast, northwest, southeast, southwest);
- Practice patterns (both in terms of setting and technique preferences);
- HMO penetration rate (both in terms of the general population, as well as the Medicare population);
- ASC penetration rate; and
- Per capita income.

Exhibit 1.3 presents some of these demographic and 'environmental' data for all states. Variation in these criteria would increase the generalizability of any evaluation findings. On the other hand, sufficient data were needed to analyze separately the effect of these differences. If only three geographic areas were pursued for the demonstration, then it would be most useful to focus on only the most important variables. These would likely be regional variation (given practice pattern differences) and ASC penetration (given the variation in rates charged by ASCs and OPDs and the perceived greater efficiency of ASCs).

While all these considerations were used in the design and execution of the area selection process, the two variables that received the most weight in the final selection process were: variation in ASC penetration rates, and Medicare charge levels for major cost components (surgeon's fees and facility charges) of cataract surgery. On the cost criteria, it was felt that limiting the demonstration to high-charge areas would reduce the generalizability of the findings. It was decided that charge patterns should either vary across sites or areas with average charge levels should be selected. It was also decided that given the limited nature of the demonstration and the small volume of cataract surgery performed in rural areas, it would be unwise to devote an entire site to a rural area.

The decision to use MSAs as the area for the demonstration resulted in a choice of over 150 metropolitan areas from which to choose the treatment and control sites. After reviewing volume, costs, ASC penetration and other variables across all these potential sites, HCFA initially selected Albany/Troy, NY, Cleveland, OH, and Dallas/Ft. Worth, TX, as the three sites for the demonstration. However, due to low response rates to the request for applications from providers in the Albany area, HCFA decided to drop Albany and replace it with Phoenix, AZ as the third demonstration site.

Exhibit 1.4 displays how these three final areas compare to national level norms for the major variables used in site selection. In terms of Medicare enrollees, Cleveland was the largest of the demonstration sites, followed closely by Phoenix (with its high number of retirees) and Dallas with about 100,000 fewer beneficiaries than Cleveland. On this demographic measure, all demonstration areas provided adequate numbers of enrollees to provide sufficient volume of cataract surgeries over the demonstration period. In terms of the volume of surgical procedures, the most telling measure on the exhibit is the ratio of surgeries per beneficiary in each MSA. Both Cleveland and Phoenix exceeded,

Exhibit 1.3
1988 Demographic Characteristics By State

STATE	Number Cataract Surgeries Per Ophthalmologist (C)	Number Cataract Surgeries Per Medicare Beneficiary (D)	Number Ophthalmologists per 10,000 Population (I)	Number Ophthalmologists per 10,000 Rural Population (I)	Percent Population Enrolled in HMO (K)	Percent Medicare Population Enrolled in HMO (L)	Per Capita Income (M)	Number of ASCs (N)
Alabama	104	0.04	0.40	0.18	2.4	1.3	9.6	18
Alaska	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Arizona	84	0.04	0.61	0.21	15.5	10.9	11.6	68
Arkansas	78	0.03	0.49	0.26	0.9	0.4	9.7	12
California	33	0.02	0.67	0.54	26.6	19.2	14.0	213
Colorado	44	0.03	0.64	0.33	13.6	10.3	13.1	18
Connecticut	39	0.02	0.76	0.50	10.1	2.9	16.3	13
Delaware	59	0.03	0.51	0.28	10.5	0.3	12.6	N/A
Washington D.C.	80	0.10	1.34	•	50.0	4.1	16.0	3
Florida	89	0.04	0.69	0.35	8.6	11.4	12.2	80
Georgia	74	0.04	0.46	0.26	4.8	0.5	11.2	17
Hawaii	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Idaho	46	0.02	0.45	0.41	0.1	0.4	10.0	8
Illinois	62	0.03	0.54	0.34	11.7	6.3	13.3	44
Indiana	90	0.03	0.42	0.17	6.5	3.9	11.3	23
Iowa	75	0.02	0.45	0.23	6.3	3.2	11.5	5
Kansas	59	0.02	0.44	0.27	6.8	6.6	13.0	13
Kentucky	71	0.03	0.41	0.22	3.8	3.6	9.9	13
Louisiana	66	0.05	0.69	0.20	2.8	0.1	9.9	32
Maine	67	0.02	0.46	0.43	0.2	0.2	10.8	6
Maryland	24	0.02	0.80	0.38	10.2	1.5	13.8	44
Massachusetts	46	0.03	0.74	0.52	18.1	7.4	14.5	12
Michigan	79	0.03	0.48	0.22	14.3	4.3	12.2	14
Minnesota	32	0.02	0.62	0.27	20.7	31.9	12.6	10
Mississippi	99	0.04	0.44	0.31	0.0	0.1	8.6	9
Missouri	84	0.04	0.55	0.13	8.4	2.8	11.7	20
Montana	15	0.01	0.52	0.46	0.0	0.4	10.2	9
Nebraska	73	0.03	0.48	0.24	3.6	1.9	12.0	2
Nevada	81	0.03	0.38	0.24	11.5	17.9	12.6	11
New Hampshire	49	0.02	0.56	0.66	10.2	1.3	13.3	5
New Jersey	49	0.03	0.65	•	8.0	3.7	15.2	25
New Mexico	57	0.03	0.41	0.31	9.6	11.3	9.8	6
New York	28	0.02	0.87	0.39	10.4	6.1	14.2	17
North Carolina	84	0.04	0.49	0.30	4.8	0.2	10.6	27
North Dakota	140	0.04	0.40	0.12	5.7	2.2	12.1	5
Ohio	64	0.03	0.52	0.23	10.4	2.4	11.9	29
Oklahoma	109	0.04	0.41	0.17	4.6	1.6	10.9	18
Oregon	56	0.03	0.66	0.46	17.6	16.7	11.2	11
Pennsylvania	59	0.03	0.64	0.35	7.7	3.4	11.9	26
Rhode Island	88	0.03	0.48	•	16.4	2.8	12.8	3
South Carolina	64	0.03	0.43	0.26	5.2	0.8	9.8	13
South Dakota	116	0.03	0.35	0.33	0.4	0.6	10.8	4
Tennessee	75	0.03	0.52	0.20	3.8	1.0	10.4	30
Texas	81	0.05	0.50	0.24	5.2	0.4	11.7	90
Utah	10	0.01	0.58	0.24	14.3	2.1	9.3	10
Vermont	61	0.03	0.54	0.48	1.3	0.2	10.7	N/A
Virginia	21	0.01	0.46	0.37	5.4	1.5	13.4	12
Washington	63	0.03	0.56	0.42	9.4	9.5	12.7	37
West Virginia	90	0.03	0.42	0.37	2.2	13.1	9.4	6
Wisconsin	51	0.02	0.54	0.24	21.5	1.7	11.8	11
Wyoming	14	0.01	0.40	0.35	0.3	1.5	12.1	1
Total U.S.	55.5	0.03	0.59	0.30	11	7	12.5	1,103

N/A Not Available
• No rural areas in these states, as defined by Medicare locality rural areas.

Source: County and State Area File, Prospective Payment Analytic Support Studies, Abt Associates, 1998.

Exhibit 1.4

Volume, Cost, and Demographic Characteristics of Demonstration Areas

MSA Name	Total Number of Medicare Beneficiaries[1]	Number of Cataract Surgeries[2]		Number of Ophthalmologists[3]		Average Allowed Charges Per Primary Surgeon[2]	Percent Cataract Surgeries Performed In:[2]			
		Total	Per Beneficiary	Total	Per 10,000 Medicare Beneficiaries		Office	OPD	ASC	Other
Cleveland	350,673	13,410	0.038	200	0.175	$1,324	2	89	6	3
Dallas	253,049	7,802	0.030	326	0.077	$1,342	11	41	30*	18*
Phoenix	325,448	12,620	0.038	237	0.137	$1,389	11	23	65	1
National Norms (where available)	—	—	0.030			$1,311	6	68	17	8

1. 1990 Medicare Enrollment File, HCFA.
2. Figures are for procedures performed in 1991. Source: Part B Medicare Annual Data (BMAD) Procedure File.
3. Figures are for 1990. Source: Area Resource File (ARF).

*Estimates based on 1993 BMAD Procedure File Data.

while Dallas matched the national norm for this measure. On the cost measure, all three demonstration areas had mean allowed charge levels for the primary surgeon that were above national averages, although none exceeded the national mean by more than 6 percent. Finally, there was a good variation among the sites on the locus (settings) of these surgical episodes. Dallas and Phoenix had considerably higher proportions of these procedures performed in ASCs than the national average, while Cleveland was about two-thirds below the national average. Thus, in terms of the two key variables used in site selection — charge levels and ASC penetration rates — demonstration sites were all slightly above national norms on the cost measure while offering adequate diversity on the facility measure.

This concludes our discussion of the major objectives and design features of the demonstration. In the next chapter we review the procurement stage of the demonstration and include brief profiles of the provider entities whom HCFA selected to participate in the demonstration.

2.0 Selection of Demonstration Participants: The Procurement Process

2.1 Introduction

This section describes the two-stage process HCFA conducted over the 1991-1992 period to solicit and evaluate applications from provider organizations to participate in the demonstration. Stage 1, the Pre-Application Process, is discussed in Section 2.2.1 and Stage 2, the Final Application Process, is described in Section 2.2.2. Descriptions of the four provider organizations who were selected by HCFA to take part in the demonstration appear in Section 2.3. However, before beginning the discussion of the procurement process, it is important to describe an important challenge to the demonstration which was taking place at the same time in the legal arena.

Ophthalmologists Sue HCFA

From the time HCFA announced the project in 1989 it had been actively opposed by most organized segments of the ophthalmologic community. When it became apparent to these groups in 1991 that the project would move forward despite their opposition, a lawsuit was filed on May 1, 1991 in the United States District Court for the Northern District of Ohio Eastern Division by the national ophthalmologic medical society, the American Academy of Ophthalmology, and by the Cleveland Ophthalmological Society for declaratory and injunctive relief against the Secretary of the U.S. Department of Health and Human Services (DHHS) and the Administrator of HCFA. The initial complaint by the plaintifs included the following six charges (counts) concerning the demonstration:

Count I: that it exceeded the defendants' waiver authority for Medicare experiments and demonstration projects;

Count II: that the defendants failed to give proper weight to the advice and recommendations of specialists competent to evaluate the demonstration;

Count III: that the demonstration violated the Medicare Fraud and Abuse statute;

Count IV: that the demonstration violated Medicare freedom of choice provisions;

Count V: that the demonstration enabled the defendants to exercise illegal supervision over the practice of medicine; and

Count VI: that the demonstration denied ophthalmologists equal protection of the laws in violation of the due process clause of the fifth amendmant of the Constitution.

The suit dragged on for over a year with both sides filing various motions and two other medical societies attempting to join the suit. The plaintiffs first filed a motion for preliminary injunction with a memorandum in support. The Court declined to rule on the preliminary injunction motion, waiting to address the plaintiffs' claims on summary judgment.

DHHS and HCFA responded to the plaintiffs' complaint by filing a motion to dismiss the plaintiffs' complaint for lack of subject matter jurisdiction. Both sides submitted memoranda in support of their respective positions. The Court overruled the defendants' motion to dismiss, finding that the plaintiffs' claims were ripe for review and that the plaintiffs had standing to assert them. Upon leave of the Court, the defendants filed an answer to the plaintiffs' complaint in the form of a general denial.

The American Society of Anesthesiologists then approached the Court to intervene as a plaintiff in the case; however, the Court overruled the motion to intervene. The Academy of Medicine of Cleveland subsequently moved the Court to intervene as a plaintiff in the case, and the Court granted its motion to intervene. As a result, the Second Amended Complaint in Intervention was filed, wherein the Academy of Medicine of Cleveland joined in each of the allegations asserted by the plaintiffs in the complaint.

The plaintiffs subsequently filed a motion for partial summary judgment, asserting that they were entitled to judgment as a matter of law on Counts I, III, IV, V, and VI of the complaint. DHHS and HCFA responded by filing a motion for summary judgment in which they argued that they were entitled to judgment as a matter of law on all six counts of the plaintiffs' complaint. The Court heard oral argument on the summary judgment motions.,

The complaint was concluded on June 10, 1992 when Senior Judge Alvin I. Krenelor issued his opinion and order granting DHHS' and HCFA's motion for summary judgment on all the counts of the complaint and overruling the plaintiffs' motion for partial summary judgment.

On July 10, 1992, the plaintiffs appealed the District Court decision to the U.S. District Court of Appeals for the Sixth Circuit. The appeal was argued on May 3, 1993 and the Appeals Court decided and filed its opinion on July 9, 1993, affirming the District Court's decision and order. Plaintiffs requested a rehearing before the Appeals Court which the Court denied on August 24, 1993.

Although DHHS and HCFA were ultimately successful in court, the suit generated additional negative publicity for the demonstration and may have further discouraged providers from participating in the project. This opposition, as we shall see below, also contributed to the very low response rates to the project's solicitation process in demonstration locations. While we will have more to say about the reasons for this opposition later in this section and in Section 5.0, the reader should be aware that these factors were in operation at the same time as the solicitation process.

2.2 The Procurement Process

HCFA conducted a two-stage procurement process in these MSAs over the 1991-1992 period to solicit and evaluate applications from provider entities to participate in the demonstration. The two-stage process consisted of:

- Stage One — a Request for Pre-Applications from institutional (hospitals, ASCs) and professional (ophthalmologists) providers in the demonstration areas for expressions of interest and summaries of qualifications for participating in the demonstration;

- Stage Two — a Request for Final Applications, with detailed experience and qualification data and proposed package prices from the most qualified provider entities among the pre-applicants in each demonstration area.

The two-stage procurement process was intended to reduce the overall burden on providers in applying to participate in the demonstration. The simplified pre-application phase allowed providers to assess their interest in and capabilities for participating in the demonstration.

This chapter will describe the methods used by HCFA to conduct each stage of the procurement process. The chapter concludes with summary profiles of providers selected by HCFA to participate in the demonstration.

2.2.1 The Pre-Application Process

One of the unique aspects of the demonstration was that it represented one of the first attempts by Medicare to engage in tests of bundled payment approaches with organizations representing the major facility/professional provider types involved in the broad scope of care surrounding an episode of surgical care. [HCFA's other bundled payment demonstration for CABG surgery was just becoming operational in the Spring of 1991 when the cataracts pre-application process was underway.] Because of the novelty of this initiative, HCFA took care to provide examples of possible provider configuration arrangements in the Overview of the Design and Application Process which was included in the pre-application packages mailed to prospective providers in demonstration areas. Among the examples of physician/facility alliances cited in the document were:

- A hospital outpatient department or ambulatory surgery center submits an application on behalf of the facility and all, or a subset of, physicians, nursing, and paraprofessional staff agreeing to participate in the demonstration.

- An individual or consortium of physicians submit an application with agreements from one or more facilities (hospital OPDs and/or ASCs).

HCFA also was flexible in allowing both existing and newly-formed entities to submit applications to participate in the demonstration. Under the examples discussed above a sharp distinction was made between the lead as opposed to the other affiliated entities involved in an application. Much would be expected of the lead provider entity while little, except, of course, the provision of good quality care, would be required of the other affiliated providers. The major responsibilities of the lead provider entity included:

1. Collect, organize, and submit all application materials (during each step of the process) to HCFA on behalf of affiliated providers.

2. Negotiate with HCFA on the bundle price and with other providers in the alliance on their respective shares of that price.

3. Submit all related claims on behalf of affiliated providers to Medicare for payment. (As discussed in Chapter 3, this turned out to be a problematic process once demonstration operations began.)

4. Allocate and disburse payments to affiliated providers.

5. Submit all other documentation to HCFA and its contractors for operations monitoring and evaluation purposes.

In return for performing these administrative responsibilities, the lead provider entity was also responsible for reimbursement to its affiliated providers.

Also included in the pre-application package mailing was a 16-page Pre-Application Document requesting detailed information about the structure, capabilities, surgical volumes and outcomes, fee-for-service and alternate payment (i.e., managed care, etc.) reimbursement experience, medical management and quality assurance programs of applicants. Applicants were also asked to discuss the approximate discount (in relation to current Medicare payment levels) they expected to offer Medicare if selected to participate in the final round of applications.

HCFA's major goal for this initial stage in the procurement process was to obtain a group of well-qualified providers with whom it could engage in serious price negotiations in the second stage of the solication process. The preponderance of information requested about providers' qualifications and cataract surgery experience and the paucity of data requested about providers' proposed prices for the bundle testifies to this goal.

Results of the Pre-Application Process

Simply mailing the pre-application packages was a sizeable undertaking. All told, over 1,000 packages were sent to providers of record (i.e., those with cataract surgical claims in Medicare in the previous year) across the four sites. More interesting and, in hindsight at least, quite revealing, is the exceedingly low response rate across sites to the initial solicitation effort. Across the four sites, only 38 applications were received, for a combined response rate of 3.7 percent. The number of applications received on a per site basis were: 20 in Dallas/Ft. Worth; 10 in Cleveland; 5 in Phoenix; and 3 in Albany/Troy. While these low response rates certainly reflect the degree to which the ophthalmic community mistrusted and opposed the demonstration, they also probably reflect the perceived intangible rewards offered by HCFA to potential provider participants. In return for agreeing to accept a lower overall payment from Medicare, providers were told they would be allowed to call themselves "Medicare Designated Cataract Surgery Providers," so deemed by Medicare due to their high efficiency and rigorous utilization and quality review standards.

Pre-applications received from providers were evaluated and scored by a HCFA review panel. Of the 35 pre-applications received from providers in the final three demonstration areas, 29 were judged to meet demonstration criteria and to warrant an invitation to submit a final application. This high acceptance rate indicates that despite the low response rate to the initial solicitation, the pre-applications that were received were generally of a high quality.

2.2.2 The Final Application Process

HCFA sent final application packages to the 29 providers whose pre-applications met the demonstration criteria. Besides the cover letter, the final application comprised two sections: 1) a summary of demonstration design and review criteria, and 2) a detailed outline section containing instructions for completing the application. Although the final application contained many of the same

sections as the pre-application, its format required more narrative as opposed to fill-in-the-blank responses from providers, and in general required providers to provide much more detail than the earlier package. Major areas requiring such detail included:

- ***Beneficiary Incentives*** — how providers planned to attract beneficiaries and what additional services, if any, they planned to offer them.

- ***Proposed Package Price*** — much more detail down to the level of individual procedure codes for physicians about how providers priced their proposals, including such key considerations as whether some or all complications were included in the price and whether the provider offered discounts when certain volume thresholds were reached.

- ***Marketing Plans*** — how providers planned to market the demonstration to beneficiaries and referring physicians and optometrists.

- ***Quality of Care*** — formal protocols describing this process were required.

- ***Medical Management*** — formal protocols describing this process were required.

- ***Utilization Controls*** — formal protocols describing this process were required.

In addition, in the package HCFA identified the following three factors that would be emphasized in the evaluation process:

- ***High Participation Rates Among Ophthalmologists*** — while all surgeons currently affiliated with a facility were not required to participate, those applications with a high proportion of participating surgeons were preferred.

- ***All-Inclusive Global Fees*** — applicants whose proposed prices for the bundle included coverage for all complications commonly associated with cataract surgery were preferred.

- ***Volume Discounts*** — while HCFA did not want to discourage small providers from participating, it recognized that larger providers may enjoy scale efficiencies that should enable them to include discounts if they experienced significant volume increases during the demonstration. HCFA indicated it would consider favorably proposals from large providers that incorporate a volume-related discount (i.e., greater discounts at higher volume levels) to reflect these efficiencies.

HCFA's selection criteria for participating providers considered a number of factors in addition to the proposed price for the bundle. In fact, factors such as beneficiary access to quality care, historical practice patterns, and utilization and quality safeguards, in the aggregate, received considerably more weight in the evaluation process than did proposed price.

Results of the Final Application Process

HCFA received a total of 21 final applications from the 29 providers invited to participate in this process. Of these, six provider organizations were selected as finalists for negotiations with HCFA. Of the six finalists, two providers withdrew from negotiations, and HCFA successfully negotiated final package prices and other terms and conditions of participation with the remaining four provider organizations. In these negotiations, which were handled entirely by HCFA ORD project officials, the following important issues were finalized in addition to the price for the cataract surgery episode:

- ***Complications*** — HCFA negotiated with the four organizations to include coverage for all common complications of cataract surgery in their bundle prices, even though some had originally proposed to exclude coverage for some or all of these outcomes in their bundled prices.

- ***Annual Price Updates*** — The bundled prices HCFA negotiated with the sites were for Calendar Year 1992. During the negotiations, the sites agreed that these prices would remain in effect for 3 years and would be adjusted January 1 of each year according to annual updates in: 1) the Part B physician fee schedule; 2) the Medicare ASC rates; and 3) the Medicare prospective payment rates for inpatient operating costs (used as a proxy for outpatient costs). Each update would be applied to the appropriate prorated portion of the total package price.

- ***Review of Marketing Materials*** — All materials and activities, including press releases and other public announcements and programs, were subject to prior approval of HCFA.

- ***Implementation Plan*** — All sites agreed to prepare a formal plan for startup and operations of the demonstration within a specified time period to HCFA.

- ***Monitoring and Evaluation*** — Sites agreed to submit quarterly progress reports to HCFA and to comply with all the requirements of the project for monitoring, audit and evaluation purposes.

Actual demonstration operations began for three providers in April 1993 and for one provider in May 1993. Brief profiles of the four participating provider organizations appear in the next section.

2.3 Description of Participating Provider Organizations

Exhibit 2.1 below presents a summary of the composition of the four provider organizations selected to participate in the demonstration. Figures in the exhibit indicate that in two of the demonstration areas, Cleveland and Phoenix, the provider organizations are led by physician group practices. This seems natural since, in most instances, the ophthalmologist is the point of entry for patients into the cataract surgery episode. In addition to determining the need for cataract surgery, the ophthalmologist schedules the surgery and coordinates the entire process from pre- to post-operative care with the patient, facility, and other specialists who may be needed. Dallas is the only location where a facility, in this case one of three area hospitals all owned by a national hospital chain, is the lead organization.

In terms of the locus of the surgery there is an ample mix across demonstration areas, with six hospital outpatient departments and two ASCs represented in the provider configurations.

Brief descriptive profiles of the four provider organizations selected by HCFA to participate in the demonstration appear below.

Cataract Eye Center of Cleveland, Inc. The lead provider entity for this organization, hereafter referred to as Cataract Eye, is a professional physician group practice corporation consisting of two ophthalmologists. Cataract Eye performed, on average, over 800 cataract surgery cases per year. It has four offices in the Cleveland area, with its main office located downtown in a medical office building adjacent to St. Vincent Charity Hospital and Health Center, which, until the last year of the demonstration, was the sole facility where surgeries were performed for demonstration patients of this provider organization.

Exhibit 2.1

Composition of Demonstration Providers

MSA/Demonstration Provider	Type of Lead Provider	Number of Facilities		
		Hospital OPDs	ASCs	Number of Surgeons
Cleveland, OH				
Medical Eye Associates	Group Practice	2	1	4
Cataract Eye Center of Cleveland	Group Practice	1	0	2
Dallas/Ft. Worth, TX				
Doctors Hospital of Dallas	Hospital	3	0	7
Phoenix, AZ				
Southwestern Eye Center	Group Practice	0	1	5
TOTAL		6	2	18

St. Vincent Charity Hospital is a tertiary institution and level one trauma center located in the downtown inner city area. In 1989, approximately 2,500 surgical procedures were performed in St. Vincent's outpatient department. Approximately 40 percent of these were ophthalmic procedures. Two of its twelve operating rooms are used for ophthalmology, where an average of 13 cataract surgeries per suite were performed each week. Thus, with a 42 percent utilization rate for eye rooms at the beginning of the demonstration, it had sufficient excess capacity to meet any volume increase resulting from the demonstration. In addition to operating suites, St. Vincent's also provided the surgical nurses and discharge planners, and social worker support services, if needed, to the provider organization.

Anesthesia services were provided by Northcoast Anesthesiologists, Inc. which had a contract to staff the anesthesia division of St. Vincent's.

Needed services of physician specialists and key paraprofessional staff would come from within Cataract Eye or through outside consultants when required.

Medical Eye Associates, Inc., the lead provider entity for the other Cleveland participating provider organization, is a professional physician group practice corporation consisting, at the beginning of the demonstration, of four physician equal partners in the practice. Later in the demonstration, Medical Eye sold its practice to Innova Medical Services, Inc.

Combined, the four physicians had performed about 270 cataract surgery procedures in 1990. Medical Eye has three offices in the Cleveland area serving primarily the western part of Cuyahoga County and the adjoining portions of Medina and Lorain Counties.

Included in its application were three facilities. These include two local area hospitals: Deaconess Hospital of Cleveland and Parma Community General Hospital, and The Surgery Center, a free-standing ambulatory surgery facility. Parma and Deaconess are private general hospitals located 4 and 6 miles, respectively, from Medical Eye's office. The Surgery Center is located approximately 3½ miles from its office. These three facilities form a triangle with Medical Eye's main office in the center. Medical Eye performs all of its private cataract surgeries, as well as corneal transplants, retinal detachments and most other eye surgeries at these three facilities. Each facility provides van service for surgery patients.

Also included in the application were the anesthesia departments of each of the three facilities. These were, in fact, private practice groups which have exclusive anesthesia contracts with those facilities. All of the physicians in each anesthesia department agreed to join the demonstration project.

Doctors Hospital of Dallas. The organizations included in this application were Doctors Hospital of Dallas, RHD Memorial Medical Center and Trinity Medical Center — all three facilities are located in the Dallas area and were owned and operated at that time by National Medical Enterprises, Inc., a national for-profit hospital chain. (The hospitals are now owned by Tenet Healthcare Corp., one of the largest national for-profit chains.) Of the three hospitals, Doctors Hospital had the highest volume of cataract surgeries and had the greatest number of participating ophthalmologists. Therefore, Doctors was selected by NME to serve as the lead hospital under the demonstration.

Seven ophthalmologists with staff privileges in these hospitals are included in the provider configuration. Participating physicians are private practitioners. All physicians are independent of the hospitals, with privileges to perform cataract surgeries at their respective facilities. Two of the surgeons are in partnership practice, with the remaining surgeons in private, solo practice. The seven cataract surgeons involved in the team combined to perform slightly under 1,300 cataract surgeries in Medicare in 1990.

When the demonstration began, cataract surgery teams had been assigned at Doctors Hospital and at RHD. Since the third hospital, Trinity Medical Center, did not have an ophthalmologist on staff, a demonstration team had not been selected for that facility when the project began. However, an ophthalmologist was expected to be recruited by mid-summer, 1992, and the cataract team at Trinity Medical Center would be established then for the demonstration.

Southwestern Eye Center, Ltd., is the lead and only provider entity for the participating provider in the Greater Phoenix area. Southwestern Eye is a physician professional corporation group practice with headquarters in Mesa and about eight other offices in the Phoenix/Mesa area as well as other parts of the state. Five ambulatory surgical centers (ASCs) are included in these locations, including the main ASC proposed for the demonstration located at the Dobson Road Facility in Mesa. With the exception of three contracted retina vitreous specialists, all physicians, certified registered nurse anesthetists and other staff proposed for the project were salaried employees of Southwestern Eye.

This concludes our discussion of the methods used in the procurement process of the demonstration and the outcomes of that process. In the next section we discuss some of the administrative issues encountered by participating providers during the project's start-up and operational period and our findings related to the volume and savings outcomes of the demonstration.

3.0 Impacts of the Demonstration on Participating Providers in the Start-Up and Operations Period

3.1 Introduction

This section describes the impacts of the demonstration on participating providers during the implementation and operational periods of the project. Only non-clinical impacts are addressed in this chapter. The impacts of the demonstration on clinically-related issues, such as the types, mix and number of services beneficiaries received from participating providers, and the impact of these services on patients' visual acuity and other outcome measures are addressed in detail in Section 4.0.

For the most part, information for this section came from two major sources: 1) interviews with officials and staff of demonstration providers during two waves of site visits in 1992 and 1994, supplemented by other interviews published in the trade industry press; and 2) information on claims volume from the patient checklists completed by demonstration providers combined with records of bundle claims submitted by these providers to HCFA.

The remainder of the section is organized as follows. Section 3.2 describes the administrative challenges relating to internal coordination among affiliated providers and claims submission/payment issues experienced by participating providers during the start-up and operation period. Section 3.3 describes the actions taken by demonstration providers to reduce costs and make the provision of bundle services more efficient. Section 3.4 describes the marketing campaigns launched by providers and the success and failures of these efforts to increase the volume of cataract surgery within the organization. Section 3.5 concludes the chapter with a discussion of the bundled prices paid by Medicare to the participating providers during the three years of the demonstration.

3.2 Demonstration Start-Up and Operations

Coordination Among Affiliated Providers

Once the demonstration began, most lead provider entities reported typical administrative problems in establishing mechanisms within the configuration for 1) scheduling appointments with affiliated providers for particular services of the bundle, particularly in establishing dates for the surgical procedure; and 2) receipt of claims for specific services of the bundle from affiliated physicians and facilities in order to submit consolidated billings for the bundle to HCFA.

Some providers also required some time to work out procedures for completion of respective portions of patient checklists by affiliated providers during the four-month period covered by this document. By the time of our second wave of visits to these provider locations in the spring of 1994, most of these coordination problems had been resolved by the providers. However, all provider entities we interviewed, whether lead or affiliated entities, but especially the former, reported that the simple task of collecting all relevant claims from all providers involved in the bundle episode and submitting these patient-specific claims in a complete package to HCFA was a more time-consuming and involved process than they had originally anticipated. Until these administrative procedures were formalized, some service-specific claims were submitted in error to the regular Medicare carrier or intermediary. Generally such mistakes decreased significantly as the operational period of the demonstration progressed.

Reimbursement Difficulties

One problem that all provider organizations reported when the demonstration began and that persisted to a lesser degree throughout the project involved receiving payment from supplemental insurers for the beneficiary coinsurance and deductible amounts (i.e., the beneficiary liability portion of the bundle price). This was a major problem for all providers because such a high proportion (over 75 percent) of Medicare beneficiaries carry some type of Medicare supplementary insurance. Although these policies vary in their coverage and payment provisions, virtually all such policies cover the annual deductible and 20 percent coinsurance amounts which are basic features of the Medicare Part B program. All the services included in the cataracts surgery bundle, including the facility charges from hospital outpatient departments and ASCs, are Part B-covered services. In the demonstration, HCFA used an internal agency, the Division of Research and Demonstration Systems Support (DRDSS) as a surrogate Medicare contractor (fiscal intermediary/carrier) to receive and process bundle claims and issue payments to participating providers. Under this arrangement, after DRDSS verified the beneficiary's eligibility and Part B deductible status and issued the bundle payment to demonstration providers (usually within 30 days), it sent the individual facility and physician claims for bundle services to a designated Medicare fiscal intermediary (FI) for additional processing. The FI entered the records for the services into the Medicare Common Working File (CWF) to update each beneficiary's utilization history and then would send an Explanation of Medicare Benefits (EOMB) to each bundle provider for use in billing Medicaid and other supplemental insurers for the Part B coinsurance and deductible amounts.

Although no providers experienced significant problems in the turnaround time for receiving the bundle payment from HCFA, all had significant problems in their ability to bill and collect payments from supplemental insurers (including state Medicaid programs). Their problems were twofold. First, it took about 60 days (after the bundle payment was received from HCFA) for providers to receive the EOMB from the FI in order to bill supplemental insurers. Thus, it was generally three months after surgery before providers could bill for Medicare copayment and deductible amounts. Second, the EOMB they received from Medicare for the bundle payment was unique; it looked and was formatted differently than a traditional EOMB and did not contain line item detail, including the usual procedure codes, of submitted, allowed, and paid amounts for individual services received by the beneficiary. The processing systems of most supplemental insurers had evolved over the years to rely on procedure code-specific line item detail on the EOMB (or its electronic media equivalent) to apply coverage and reimbursement screens to Medicare claims. In place of such detail, supplemental insurers were confronted with an EOMB that consolidated all services to one line item and charged a uniform copayment amount based on the bundle price HCFA negotiated with each provider.

Naturally, most supplemental insurers, particularly at the beginning of the demonstration, refused to honor the EOMB. They said it lacked the required detail and was incompatible with their processing systems. At the demonstration provider level, the problem was compounded by the large numbers of different supplemental insurers marketing to beneficiaries in each location.

In response to this problem, HCFA project staff mounted several efforts to encourage supplemental insurers to honor the EOMB. They developed a letter explaining the demonstration that participating providers could include with the unique EOMB in billing supplemental insurers. The letter emphasized that in most cases, the copayment amounts were lower under the demonstration than they would be under the regular Medicare fee-for-service program. HCFA also contacted insurance commissioners in each demonstration state to request their assistance in persuading the insurers to honor bundle claims. Third, HCFA contacted the national Blue Cross Blue Shield Association and persuaded it to issue a memo to Medigap officials in member plans explaining the unique features of

the project and its EOMB, and requesting their cooperation in honoring its complementary claims. Of course, not all supplemental insurers were "Blues" plans.

Although all these concerted efforts, not to mention those of the providers' billing staffs themselves, had some success, the problem was never entirely eliminated during the demonstration. However, as the project progressed and increasing numbers of Medigap insurers became familiar with the bundle EOMB, provider billing staff began to gradually devote less time and other resources to the supplemental claims reimbursement effort.

3.3 Cost Reduction Initiatives of Participating Providers

One of HCFA's major objectives for the demonstration was to "provide incentives to manage patient care so that cost efficiencies are realized and the procedure can be performed at a lower cost." Two key features of the demonstration were seen as providing such incentives. The lead/affiliated provider feature of the project, involving all major facility and professional entities dispensing care for components of the bundle was supposed to encourage better coordination and management of care for demonstration patients and, in theory at least, lead to lower per case costs overall. The second and stronger feature was the obvious one, the basic discount included in the bundled price.

During our site visits in 1994 we asked participating providers if in fact they have taken any specific actions to reduce their costs for the cataracts episode after their first year experience with the demonstration. Officials and staff of three of the four participating providers cited anecdotal information that such actions had been taken. They are summarized below:

- One provider reported that at least one physician had made changes in his surgical technique with foldable lenses, smaller corneal incisions, and use of dissolving sutures. These changes had cut surgery time in half and permitted him to see patients less often after surgery. This had made the procedure itself more efficient and reduced the number of post-operative patient visits required in the typical case. There were also indications that one of the hospitals involved in this provider configuration had made changes in its method, agent, and staffing arrangements for anesthesia services associated with the surgery to reduce costs.

- Another provider standardized the entire package of materials used in the cataracts surgical procedure (medications, surgical instrument and supplies, the IOL, and pre-/post-operative medications) so it could purchase a tailored package of these materials at a discount price from one vendor for all its cataracts surgery patients, demonstration as well as non-demonstration patients.

- A third provider had standardized the IOL it used for cataract surgeries. This provider also cited other, less tangible cost-efficiency benefits of its participation in the demonstration during our site visit. It noted the demonstration had prompted the practice to examine, for the first time, its costs per episode of cataract surgery at the individual surgeon level. This and other related moves placed the practice in a better position to compete for managed care business.

A key question about the initiatives discussed above is whether or not they can be listed as true impacts of the demonstration. Put another way, might they have taken place in the absence of the demonstration? The obvious answer is yes. In citing these initiatives we are in no way implying they are *direct impacts* of the demonstration. In fact, they are the exact type of actions one would expect any progressive provider to be initiating on an ongoing basis to reduce costs and improve the value of the service it delivers to its patients and payer clients. In relation to causality, the best one might say is

perhaps the discount feature of the demonstration provided an additional reason, beyond those already operating in the healthcare marketplace, for participating providers to search for ways to reduce costs.

3.4 Efforts to Market the Demonstration

Participating provider organizations used a variety of methods and media to publicize their selection as a "Medicare Designated Cataract Surgery Provider" in their respective locations. In general, the marketing efforts of demonstration providers were aimed at two different audiences: 1) Medicare beneficiaries; and, 2) optometrists in the local area who refer patients to cataract surgeons. The remainder of this section will maintain this target group distinction in describing these marketing efforts. Section 3.4.1 provides an overview of the types of marketing methods used by the providers to attract Medicare beneficiaries to their practices. Section 3.4.2 examines the approaches that a few of the providers used to market the demonstration to local optometrists in an effort to attract increased referral of patients. Section 3.4.3 analyzes the actual cataract surgery volume rates achieved by providers during the three-year period of the study.

3.4.1 Marketing Efforts to Medicare Beneficiaries

Demonstration providers used a variety of methods and media to inform Medicare beneficiaries about their participation in the project. Most of these efforts were concentrated over the first year or less of the demonstration. After assessing the poor results of these early efforts, all providers had ceased expending any further effort or money to publicize the demonstration to area beneficiaries after the first year of operations.

The types of media used in these marketing efforts included the following:

- ***press releases*** — a number of providers used this device when the demonstration began to publicize their selection as a designated provider. One provider looked at the possibility of hiring a public relations firm to handle its campaign but learned that most firms were not interested in an account or campaign as small as that envisioned by the provider.

- ***direct mailings*** — two of the four providers sent information material to selected groups of senior citizens in their respective areas. The size of the mailings ranged between 2,000 at one provider to 37,500 at the other provider.

- ***newspaper advertisements*** — all providers placed advertisements in major (downtown) and suburban newspapers. In addition, at least one provider placed ads in publications aimed specifically at area seniors. One provider paid over $20,000 on its newspaper advertisements in one of the early calendar quarters of the demonstration.

- ***radio/TV spots*** — three demonstration providers paid for radio and TV spots (ranging between 30 to 60 seconds) to publicize their participation in the demonstration and the benefits of the project to Medicare patients. One provider paid for over 133 TV spots over the first few months of the demonstration. This provider also had a telemarketing department available to respond to its toll-free phone number publicized in these ads. Over the first 6 months of the demonstration, it received about 140 calls on this line as a result of these ads but these resulted in only 21 actual referrals to its surgeons for cataract surgery.

- ***other outreach efforts*** — most providers also had surgeons and staff speak at senior centers and health fairs to publicize their demonstration status.

As noted earlier, results of these marketing efforts were viewed as minimal and disappointing by all demonstration providers. Most pointed to the difficulty of explaining the complex administrative features of the demonstration to area seniors. They also had difficulties in explaining the financial benefits resulting from use of participating providers. Moreover, these benefits applied to only the estimated one quarter of all beneficiaries with no Medigap coverage and even for this group the savings offered to patients of most providers were too small to attract a high number of patients. The lead cataract surgeon at one provider said he thought the demonstration was too small a project to get noticed and tended to "get lost" in all the then (1993-1994) current discussions of national health care reform in the media. Moreover, all providers thought HCFA could have done more to support their efforts by holding news conferences and issuing press releases to educate beneficiaries about the objectives of the demonstration and the benefits of their participation in the project.

While it was difficult for beneficiaries to understand the complex administrative and financial aspects of the demonstration, those who did participate appreciated one feature of the demonstration; the reduced number of benefit and payment notices they received from Medicare as a result of the bundle payment. During our 1994 interviews, all demonstration providers reported that many beneficiaries had commented favorably about receiving only one explanation of Medicare benefits (EOMB) from Medicare in contrast to the multiple EOMBs they usually received under the conventional billing and payment systems. This again is an important impact finding of the demonstration.

We noted earlier that HCFA required demonstration providers to send them all marketing materials for prior review before they were used to publicize the demonstration. This is a fairly standard requirement which HCFA has imposed in most of its demonstrations of alternate payment methods over the years. While most providers understood the rationale for this pre-review and approval requirement, some thought this review was too legalistic. To quote one participating surgeon, "...when you advertise you can't make every ad sound like a legal statement — you lose your point."[9]

3.4.2 Marketing to Optometrists and Other Physicians

Only two of the four demonstration providers made any serious attempts to develop referral networks of optometrists (and sometimes other physicians in general practice) to increase the volume of cataracts surgery cases in their practices.

One provider sent an initial letter to optometrists in its service area in early April 1993 explaining the demonstration and expressing its availability to meet with them to discuss co-management opportunities offered by the demonstration, but its success in subsequent efforts to recruit optometrists was minimal.

Only one provider experienced any measurable success in marketing the demonstration to area optometrists. Unlike the other demonstration providers, this provider employed four optometrists in its practice and had long-standing co-management relationships with a number of optometrists in its service area. Shortly after the demonstration began it sent a general mailing to ODs in its established referral network offering them an opportunity to participate. Based on responses to this mailing, it held evening informational seminars at various locations for interested ODs. It offered ODs the opportunity to begin co-managing one week after surgery after the first two post-operative visits to the surgeon. Its recruitment efforts among ODs were successful. By the summer of 1993 it had successfully recruited over 50 optometrists to participate in the project. This recruitment rate represented about 70 percent of all the ODs in its referral network before the demonstration began.

---

9 "InSight Focus: A Policy Issue Analysis from Insight Reports," Volume 10, No. 3, February 11, 1994.

3.4.3 Surgery Volumes of Participating Providers in the Demonstration

Demonstration operations began in April 1993 at all participating providers except Medical Eye, which began operations in May of that year. Medical Eye also decided at the end of 1994 to cease participating in the project. The remaining three providers stayed in the project for its full three-year term and ceased demonstration operations in March/April 1996. Exhibit 3.1 presents a summary, by provider and year, of the number of cataract surgery episodes billed by the providers to HCFA.

Volumes of episodes on a provider-specific basis varied considerably from a low of 413 at Medical Eye, to a high of over 1,800 episodes at Southwestern Eye, the highest volume provider. Southwestern Eye was also unique in that it was the only provider whose volumes increased from 1994 to 1995, the only operational period which included two full calendar years. During this period, Cataract Eye experienced a decline of 35.6 percent in its volume, while Doctors Hospital maintained fairly stable rates with a decline of only 3 episodes from 1994 to 1995.

To comment on the volume impact of the demonstration, we have to rely on anecdotal information supplied by the providers. On this issue only one provider, Doctors Hospital, reported an increase (about 10 percent) in volume during our site visits in 1994. However, the provider quickly qualified that by stating that it could not attribute this increase to the demonstration. All other providers reported no volume increases when interviewed in the 1994 site visits.

Exhibit 3.1

Number of Surgical Episodes Billed to HCFA Per Year

	Demonstration Provider Organizations			
Year/Provider	Cataract Eye	Medical Eye	Doctors Hospital	Southwestern Eye
1993	307	155	318	305
1994	367	258	457	605
1995	236	0	454	670
1996	13	0	122	299
Total	923	413	1,351	1,879

While most providers saw no increase in volume from the demonstration, or at least that could be attributed to the demonstration project, three providers reported their volume levels were stable between 1993 and 1994 in the face of what they perceived to be a diminishing market. Most thought their participation in the demonstration may have contributed to this stability. If their reflections are correct about both the demonstration's contribution and the general market, it would be an important impact.

3.5 Bundle Prices and Savings Estimates

HCFA negotiated relatively modest discounts, in the general range of 2 to 5 percent, compared to what it had paid demonstration providers under the fee-for-service system for the services included in the bundle episodes of the demonstration. The services included in the bundle episode are uniform across all provider sites and price adjustments are not allowed for differences in the ocular or general medical conditions of patients or for complications during or after surgery. During negotiations, HCFA persuaded providers to include the costs of treating complications in their price for the bundle. Across all provider sites, prices allowed by HCFA for bundle episodes (including any deductible and coinsurance amounts) averaged $2,250.01 in 1993, $2,213.54 in 1994 and $2,184.66 in 1995. The slight reductions in average prices each year reflect the fact that HCFA negotiated terms with providers that called for annual adjustments in bundle prices to reflect the changes in the Consumer Price Index (which would tend to increase prices) and legislatively mandated changes in the physician's fee schedule for cataract procedures (which would tend to reduce prices). The net effect was slight reductions in the bundled prices across the sites over the three years of the demonstration.

4.0 Clinical Impacts of the Demonstration

4.1 Introduction

This section explores the impact of the demonstration on clinical measures: the pre-operative characteristics of patients, the services they received, and the outcomes of care. It focuses on five issues: whether bundled payment caused providers 1) to enroll patients who were relatively lower risk, 2) to reduce the level of services provided to their patients, 3) to provide services more efficiently, 4) to alter the timing of services, and 5) whether the demonstration had any impact on the measurable outcomes of care, both complication rates and visual acuity.

The section uses comparisons of clinical data collected before and during the demonstration to draw inferences about its effects. The clinical data were collected via patient checklists described in more detail below.

It is important to realize that demonstration providers were not a representative sample from the provider community. They both volunteered for the demonstration and succeeded in rigorous screening conducted by HCFA. To determine the extent to which the providers that enrolled in the demonstration already differed from other providers on just those measures the demonstration sought to influence, the section begins by comparing the demonstration providers before the demonstration to a representative sample of providers. Data on the representative providers were collected in the course of the Johns Hopkins PORT study, also discussed below.

This chapter finds that the providers who enrolled in the demonstration served patients who were fairly typical according to the clinical measures used in this study. During the demonstration, one provider's patients exhibited more favorable pre-operative characteristics than had been the case at baseline; this could be the result of risk selection or recall bias. The other two providers' patients' characteristics did not change. No provider curtailed services during the demonstration: numbers of tests rose at all providers and numbers of visits rose at one provider. (More specifically, the number of optometrist visits rose more than counterbalancing a decrease in physician visits.) Two providers increased the share of their IOLs that came from their top manufacturers; this may have indicated more coordinated and efficient purchase of such items. At all providers, rates of YAG within 120 days of surgery (when providers could not bill for it separately) declined; this probably represented postponing (not eliminating) this procedure in order to receive additional revenue. No changes in outcomes could be attributed to the demonstration.

The remainder of the section is organized as follows: the research issues and data sources will be discussed in Section 4.2. Section 4.3 will compare patients of demonstration providers at baseline with a roughly representative sample of cataracts patients from the PORT study. Section 4.4 will compare patients of demonstration providers before and during the demonstration. Section 4.5 concludes with a summary of findings.

4.2 Research Methodology

4.2.1 Issues for the Evaluation

Pre-Operative Characteristics: Risk Selection

The demonstration, like any move toward prospective payment, created an incentive for providers to control the costs of care. However, this incentive was relatively mild: marginal incentives were retooled because services previously paid individually were part of the bundle, but the overall level of the bundled payment was actually quite attractive given other changes in physician reimbursement. Moreover, any incentive to cut costs was checked by an incentive to preserve quality. This is particularly important for cataract surgery because outcomes are self-evident to patients and patient referrals are the primary source of increases in volume.

Nevertheless, one way a provider can maintain low average costs and high quality is by serving a relatively healthy group of patients who have low average costs of surgery, low rates of complications, and a good prognosis for improvement. This risk selection is considered an undesirable side effect of prospective payment. In a mixed system, in which some patients are covered by prospective payment and some by traditional indemnity plans, risk selection often means prospective payment will not save money because it will cover only the less costly patients. In a prospective-payment-only system, risk selection often means patients with high expected costs will not have sufficient access to care because most providers will wish to avoid them. Thus, risk selection is the first issue this section explores.

As stated above, the primary question will be whether demonstration providers enrolled relatively healthier patients during the demonstration than they enrolled before it began. However, it is important to realize that, even at baseline, the demonstration providers were an exceptional group. They were part of the very small minority of providers that volunteered to participate in the demonstration presumably because they believed they could offer HCFA a discounted price and still maintain acceptable standards of patient care and acceptable profit margins.[10] Thus, the secondary question will be whether demonstration providers *already* enrolled healthier patients at baseline than did their peers.

Note that if indeed demonstration providers enrolled healthier patients at baseline, then the estimated effect of bundled payment may be small, simply because there was not much room for change. The average effect of bundled payment on a broad spectrum of providers could be much larger. A similar argument can also be made for the issues related to service utilization and outcomes, discussed below. It will not be repeated but the reader should keep it in mind.

Service Utilization

Lower Levels of Service

In addition to risk selection, another straightforward way for providers to control the costs of care is to trim back the services that any particular patient receives. These marginal reductions might or might not involve services that are truly necessary to patient care. Thus, the second issue is whether or not

10 Less than five percent of providers responded to HCFA's invitation to submit pre-applications. See Section 2.

providers responded to the demonstration by reducing service levels. Again, the section will investigate whether the demonstration enrolled providers that, already, at baseline provided a relatively lean package of services.

More Efficiently Provided Services

It is also possible for providers to control costs not by reducing services but by providing a given level of services more efficiently. Advocates of bundled payment argued that by combining physician and facility fees, the demonstration would align the incentives of those two parties and encourage them to communicate regarding ways to provide care more efficiently while maintaining quality. Accounts of the demonstration of bundled payment for coronary artery bypass graft (CABG) surgery suggest that that demonstration catalyzed discussion between physicians and facilities, data collection, and data analysis that led to dramatic improvements in the coordination and efficiency of care.[11] Thus, the third issue in this section is whether or not providers responded to bundled payment by improving the efficiency of their services.

Ideally, the section would probe whether demonstration providers were efficient at baseline relative to their peers. There is reason to think they would be, both because providers with lower costs stood to profit more under bundled payment and would have been more likely to volunteer and because several of HCFA's selection criteria (good working relationships between physician and facility, solid QA and UR, data collection) would have favored efficient providers. However, the nature of the comparison data does not permit examination of this issue.

Timing Services to Maximize Revenue

The cataract surgery bundle included all cataracts-related care for 120 days following surgery. On the one hand, this eliminated certain perverse incentives. For example, for one of the demonstration providers, the previous carrier policy had been to reimburse post-operative visits occurring more than 28 days after surgery creating an incentive for physicians to postpone marginal visits until after day 28. On the other hand, the new episode definition created new problems. Providers received no reimbursement for nd:YAG performed between days 1 and 120 but full reimbursement after day 121. The report investigates how much providers responded to these incentives by apparently changing the timing of their services.

The section also documents how the demonstration providers compared to their peers at baseline for those services for which data are available.

Clinical Outcomes

Certainly, bundled payment created an incentive to reduce services. However, it is not immediately clear whether or not service reduction is desirable. Many argue that with fee-for-service reimbursement and the threat of malpractice suits, standard medical practice has come to include many unnecessary tests and procedures that do not have value in terms of patient health and well-being.

---

11 "Medicare Participating Heart Bypass Center Demonstration: Final Evaluation Report, Volume I, The First Three Years," Health Economics Research, Waltham, MA, September 1995.

Thus, although service utilization is an important measure of whether providers responded to incentives, clinical outcomes are the real measure of whether these incentives and responses were desirable. Therefore, the final issue, the demonstration's effect on clinical outcomes, is one of the most important to be examined.

4.2.2 Data Sources

Patient Checklists — Cataracts Demonstration

This section is based primarily on data from the demonstration's patient checklists. Working with its medical consultants, Abt created these checklists to collect the patient-level clinical and utilization data needed for the evaluation. Each checklist had three sections: pre-operative data including preoperative pathology, tests, visual acuity, and cataract type; operative data including type of surgery, IOL, type of capsulotomy and significant intraoperative events; and postoperative data including post-operative events, visual acuity, number of post-operative visits, and etiology for patients with corrected distance acuity less than 20/25.

A member of the provider's staff filled out a checklist for each patient in the sample. The baseline sampled consisted of 778 patients randomly sampled from the demonstration providers' Medicare cataracts patients in late 1991 and 1992. For this sample, the provider's staff reviewed the patient's clinical record to complete the checklist.

The demonstration sample consisted of the 4565 patients whose claims for cataract surgery were paid under the demonstration. For this sample, the first, second, and third sections of the checklist were filled out at three separate points in time: 1) when the decision to have surgery was made, 2) immediately following surgery, and 3) at the time of the last post-operative visit.

The same questions appeared on the baseline and demonstration checklists. However, the fact that the baseline checklists were completed via medical records review while the demonstration checklists were completed during the cataract episode may have led to responses that were not consistent across the two samples. Specifically, providers might be aware of and note on checklists certain comorbidities or complications that were never entered into the clinical record; these conditions would tend to be included on demonstration checklists but excluded from baseline checklists.[12] There is some evidence that this was a problem as discussed below. However the scope of the project does not permit us to evaluate the magnitude of this bias.

Exhibit 4.1, located at the end of Section 4.0, shows the percentage of checklists that were returned from the sites analyzed in this chapter. In the baseline sample, the overall response rate was 76 percent. Site 1 and Site 4 had slightly higher baseline response rates (81 percent and 82 percent respectively) than Site 3 (68 percent). One provider, Site 2, did not return any baseline checklists.

12 Data items potentially susceptible to this type of bias include: (comorbidities) amblyopia, age-related macular degeneration, glaucoma, corneal dystrophy/opacification, diabetic retinopathy, other retinal vascular disease, (intraoperative events) posterior capsular/zonular rupture (very susceptible), vitreous loss/anterior vitrectomy, retrobulbar hemorrhage, anterior chamber hemorrhage, (post-operative events), elevated IOP, persistent iritis, cystoid macular edema, and corneal edema.

For the demonstration sample, the overall response rate was 86 percent. In the demonstration period, Site 1 and Site 3 had slightly lower response rates (84 percent and 83 percent respectively) than Site 4 (90 percent). At all providers, the response rate dropped as the demonstration went on, especially in the last year of the demonstration.[13]

The fact that a substantial percentage of checklists are missing may bias the sample. Although we have no evidence to this effect, it is possible that some providers may have avoided returning checklists for patients whose care or outcomes appeared problematic in order to protect their image with HCFA. Again, the scope of the project does not permit us to investigate this bias further but the reader should keep it in mind when contemplating subsequent results.

The checklist is attached as Appendix A of this report.

Clinical and Utilization Data — PORT

This section also compares data from the baseline sample of patient checklists to data from the Cataracts Patient Outcomes Research Team (PORT) project conducted by the Johns Hopkins University. The Agency for Health Care Policy and Research (AHCPR) funded the PORT in 1989 to study variation in cataract surgical management and the ways in which such variation might affect patient outcomes. A central component was a large-scale, longitudinal, observational study of patients undergoing cataract surgery during 1991.

The PORT study, like the demonstration evaluation, collected clinical data on patients at three points in time. Providers were asked to complete forms for PORT patients when they were notified of the patient's enrollment in the study (i.e., before surgery), within 24 hours following surgery, and approximately four months after surgery.

The PORT sample was selected via a three-step procedure. First, three metropolitan areas (Columbus, OH, St. Louis, MO, and Houston, TX) were selected to capture geographic variation in cataract surgery rates. Then, ophthalmologists within each area were stratified by volume (50 or fewer cataracts procedures annually, 51-200, 201-399, 400 or more) and a sample was drawn from ophthalmologists in each of the top three volume strata. Finally, doctors who agreed to participate were asked to recruit 14 consecutive patients into the sample.[14]

Ultimately, 72 ophthalmologists contributed a total of 717 patients with complete data to the study. Patients were enrolled in the study between July 15 and December 15, 1991, presumably with surgery shortly thereafter.

The PORT's three-city design complements the demonstration's three-city design. The three demonstration locations — Cleveland, Phoenix, and Dallas — were also chosen to capture geographic variation in cataract surgery rates, and two of them, Cleveland and Dallas, were in the same state as the PORT city with the corresponding volume.

---

13 Numbers of checklists by site are not reported to preserve confidentiality.

14 The PORT study and the PORT sample are described in more detail in Schein et al, "Variation in Cataract Surgery Practice and Clinical Outcomes," *Ophthalmology*, Vol. 101, No. 6, June 1994.

The ideal benchmark for the baseline data would be a random sample of Medicare-eligible patients within the three cities. Although the PORT was not limited to Medicare-eligible patients, this limitation can be closely approximated by restricting the sample to patients aged 65 and older. Slightly more problematic are the facts that the PORT sample was limited to patients of surgeons who were willing to participate and was skewed on the dimension of surgeon volume, most notably by the omission of patients of very low volume surgeons but also possibly by the stratification on surgeon volume and the inclusion of a fixed number of patients per surgeon.[15,16] Moreover, the PORT sample only included patients undergoing cataract surgery for the first time or for the first and second time if the second surgery occurred within four months of the first. (Many cataracts patients ultimately have surgery on both eyes.) However, there is no reason to think that these differences mean the PORT would not provide a useful benchmark for the variables of interest to our evaluation.

In many cases, the PORT and the demonstration checklists featured identical questions. In some cases, questions were worded slightly differently but were still reasonably similar. The relevant PORT instruments are attached as Appendix B of this report. Appendix C explains which PORT questions were compared to which checklist questions including any data transformations. As with the comparison of baseline and demonstration checklists, the comparison of PORT and baseline checklists may be somewhat flawed if simultaneous provider recall for the PORT and medical record review for the baseline generate data that are not comparable.

4.3 Comparison of Baseline Patients to PORT Patients

This section compares the patients of demonstration providers during the baseline period to the patients in the PORT data base in order to determine whether demonstration providers already served a relatively healthy group of patients, offered a relatively lean and efficient package of services, and/or enjoyed relatively favorable clinical outcomes. It provides benchmark data on all the variables that will be analyzed in the demonstration/baseline comparison of the next section.

4.3.1 Methodology

This section uses comparisons between the baseline sample (all three providers) and the PORT sample. For continuous and binary variables, it uses t tests to identify cases in which observed differences are statistically significant. For categorical variables, it uses Chi Squared tests. For some categorical variables, the overwhelming percentage of observations fall within two categories; in these cases, the distribution across several categories may be presented but a t test is used, normally for the second most frequent category.

---

15 Schein et al. report that "[a] comparison of recruited and nonrecruited physicians found that the two groups could not be distinguished on the basis of the number of cataract surgeries performed annually, the percent performed by phacoemulsificiation, and the average or the minimum reported wait for performance of second eye-cataract surgery. Overall, recruited phpysicians tended to have been in practice longer than non-recruited by an average of four years. However, this difference was not statistically significant within any individual volume stratum."

16 In data reported on applications for 1990, two demonstration surgeons had volumes of 50 or fewer patients per year, five had volumes between 51 and 200, four had volumes between 201 and 400, and one had a volume exceeding 400. At the same time, the baseline sample included surgeons' patients in proportion to volume (i.e., high volume surgeons contributed more patients.) To some extent these biases counterbalance each other and the net effect of the bias should not be overly severe.

The analysis of outcome measures also uses multivariate regressions in order to control for differences in patients pre-surgical characteristics known to affect outcomes. The exact specifications and results of these regressions are presented in Appendix D.

4.3.2 Results

Pre-Operative Characteristics

Under the demonstration, providers would earn higher profits on patients who were less costly to treat. As a result, one research issue is whether or not the demonstration enrolled providers whose patients at baseline already displayed above-average prognosis.

Age

Exhibit 4.2, located at the end of Section 4.0, shows the distribution by age group of baseline and PORT patients. Age is highly correlated with health status and with rates of complications in cataract surgery. In fact, the baseline patients were older than the PORT patients; the mean age of baseline patients, 75.55, is statistically significantly greater than the mean age of PORT patients, 74.57, but this slight difference is not clinically significant.

Visual Acuity

Exhibit 4.3 shows the distribution by best corrected pre-operative distance acuity in the operative eye for the baseline and PORT patients. The two groups were fairly similar; means and medians for this measure were identical. However, a statistically significantly greater percentage of baseline patients than PORT patients had pre-operative acuity that was 20/40 or better.

Cataract Type

Information on patients' cataracts is presented in Exhibit 4.4. The percentages of baseline and PORT patients with nuclear cataracts were roughly equal, 85.3 and 84.4 percent; however, the percentage of baseline patients with posterior subcapsular cataracts was lower (23.3 as opposed to 26.6 percent) as was the percentage of baseline patients with cortical cataracts (14.7 as opposed to 22.3.) Looking at the same data from a slightly different vantage point, we observe that a higher percentage of baseline patients fell into the "nuclear cataract only," the "posterior subcapsular cataract only," and the "no cataract indicated" categories while a higher percentage of PORT patients fell into the "cortical cataract only" and the multiple cataracts categories. The difference between the two distributions was statistically significant. The differences are of limited clinical importance as there is no relationship between either the difficulty or risk of cataract surgery and the type(s) of cataracts a patient has.

Significant Pre-Operative Ocular Pathologies

Exhibit 4.5 shows the percentage of patients in the PORT and baseline samples with various ocular pathologies. A higher percentage of baseline patients (69.9 percent vs. 66.6 percent) were reported to have no ocular disease other than cataract. Similarly, a lower percentage of baseline patients suffered from seven out of nine listed pathologies; these seven were: amblyopia, glaucoma, other optic nerve disease, chronic uveitis, previous retinal detachment, diabetic retinopathy, and a history of prior

intraocular surgery. In two of these cases (other optic nerve disease and prior surgery), the differences were statistically significant. However, from a clinical perspective the two populations are quite similar.[17]

Pre-Operative Characteristics: Summary

The exhibits in this section have shown that baseline patients were slightly older than their counterparts in the PORT, slightly more likely to have good (better than 20/40) pre-operative distance acuity, less likely to have multiple cataracts, and more likely to have no ocular disease other than cataracts. Despite these small differences, the two populations were clinically similar. The data do not suggest that, at baseline, demonstration providers served a disproportionate number of low risk patients.

Service Utilization

The next section concerns service utilization. At baseline, demonstration providers might already have offered a relatively lean and efficient package of services; that might have been the reason they believed they could give HCFA a discount while preserving acceptable levels of quality and profit. Note that not all service utilization questions on the checklist can be matched to items on the PORT; those that can are discussed below.

Operative Procedures

As Exhibit 4.6 shows, phacoemulsification was less common among baseline patients than among PORT patients. The distributions of PORT and baseline patients across different types of capsulotomies and different types of IOLs were similar.

YAG

Patients in the baseline sample were less likely than patients in the PORT sample to have a YAG laser capsulotomy within 120 days of surgery; specifically, 3.7 percent of baseline patients, as opposed to 8.4 percent of PORT patients, had YAG. (See Exhibit 4.7.)

Service Utilization: Summary

Services provided to baseline patients were broadly similar to the services provided to patients in the PORT. Baseline patients were less likely to have their cataracts extracted by phacoemulsification and to receive nd:YAG within 120 days of surgery.

---

17 Reported differences could also be the results of recall bias. See Section 4.3.

Clinical Outcomes

The next issue of interest is the comparison of outcomes measures between baseline patients of demonstration providers and PORT patients. HCFA's selection process was intended to ensure that demonstration participants were high quality providers.

Rates of Complications

Intra-Operative Complications

Although cataract removal is a very common and a relatively safe surgical procedure, complications can occur. Exhibit 4.8 shows the rates of certain intra-operative complications known to be associated with cataract surgery among the baseline and PORT samples. On all measures, the rates among the baseline patients are lower than the rates among PORT patients. In the case of anterior hemorrhage this difference is statistically significant. This is consistent with the hypothesis that, at baseline, the demonstration providers were high quality providers, but, as noted above, it could also possibly be the result of recall bias.

Once the data were adjusted for pre-operative pathology, pre-operative visual acuity, and age, then this difference in intra-operative complications remains but is no longer statistically significant. See Appendix D for a full presentation of regression results.

Post-Operative Complications

Rates of certain post-operative events are presented in Exhibit 4.9. In three out of four cases, the rates for baseline patients were lower than the rates for PORT patients. In the case of wound leak/rupture, the difference was statistically significant.[18]

As could be expected, the difference in the summary measure was also statistically significant with baseline patients less likely to have any post-operative events. Even when the data were adjusted for differences in patients' preoperative characteristics, baseline patients remained statistically significantly less likely to endure recorded post-operative complications.

Visual Acuity

Post-Operative Level of Visual Acuity

Most patients undergo cataract surgery in order to improve their vision, and one of the most natural outcome measures for cataract surgery is post-operative visual acuity in the operative eye.[19] Exhibit 4.10 indicates the distribution of patients across four categories of post-operative visual acuity. Higher percentages of baseline patients were in the three categories corresponding to poorer post-operative

---

18 The post-operative event questions were structured differently on the PORT and on the checklists. See Appendix C for details.

19 Although visual acuity is a natural measure, it is not the only measure. Other direct measures of vision, such as sensitivity to glare, or measures of visual function, such as ability to read small print or to drive at night, are also useful measures of the outcomes of cataract surgery. However, the only measure included on the checklist was visual acuity. The beneficiary survey, included in the original evaluation design, would have asked questions about visual function.

visual acuity (≤ 20/200, 20/100-20/80, 20/70-20/50) while a lower percentage was in the category corresponding to the best post-operative acuity. These differences translated into mean visual acuity that was statistically significantly lower for baseline patients than for PORT patients. This difference remains when one controls for pre-operative characteristics.

Change in Snellen Lines

An alternate approach to measuring visual acuity outcomes is to measure the *change* in visual acuity, as in Exhibit 4.11. By this measure, baseline patients again fared less well than PORT patients. A higher percentage experienced gains in visual acuity of 0 or fewer Snellen lines while a lower percentage experienced gains of greater than 4 lines. The difference in means was statistically significant, 4.08 for baseline patients and 4.64 for PORT patients; regression analysis yielded a comparable and statistically significant estimate.

Clinical Outcomes: Summary

At baseline, patients of demonstration providers had relatively low rates of reported complications. However, this may be an artifact of how the data were reported. Baseline patients actually had lower average post-operative visual acuity and a lower average change in Snellen lines. From the clinical perspective, these differences, although statistically significant, were small; demonstration providers' patients had clinical outcomes in line with those previously reported.

4.4 Comparison of Baseline Patients to Demonstration Patients

The preceding section showed that patients of demonstration providers were rather typical with regards to the clinical measures on the checklists. The next section will study whether notable changes occurred once the demonstration began.

4.4.1 Methodology

This section uses comparisons between baseline patients and demonstration patients at a particular demonstration provider to draw inferences about the effects of the new payment methodology. The strength of this comparison is its independence of any permanent, distinctive features of the providers. (For example, one provider might have had a surgeon with particular expertise in caring for patients with diabetic retinopathy and many patients with that condition in both the baseline and the demonstration period. Because our estimates are based on differences, they would not be affected by this distinctive feature.) However, the weakness of this comparison is that it is not possible, statistically, to sort out changes that result from the demonstration from changes that result from other, simultaneous influences at a particular provider. (To continue the example, one provider might have directed patients with diabetes elsewhere during the demonstration fearing complications and high costs, or the surgeon with this specialty might have cut back on work in preparation for retirement.) In attributing changes to the demonstration, we must rely on *a priori* hypotheses, corroborating evidence from the providers, and background information on changes in the practice of cataract surgery over this period.

Note that this issue is particularly acute for questions relating to service utilization and, to a lesser degree, to outcomes. The ocular condition of the elderly population may change relatively slowly, but the development and spread of new practices in cataract surgery (leading to changes in outcomes) may be rapid.

Because this section is devoted to the demonstration/baseline comparison, only the three sites that submitted baseline information are included. Like the first half of the section, this second half relies primarily on t tests for binary and continuous variables and on Chi Squared tests for categorical variables. Regression analysis, detailed in Appendix D, is used to supplement analyses of outcome measures. Because the outcomes information is sensitive and possibly biased, it is reported for the three sites collectively rather than individually.

4.4.2 Results

Pre-Operative Characteristics

One way for providers to increase their profits during the demonstration was to cultivate patients whose expected treatment costs were relatively low. This next section investigates whether demonstration providers' patients' pre-operative characteristics changed in a way that would indicate favorable risk selection.

Age

Exhibit 4.12 shows the age distributions at the three providers before and after the demonstration began. At no provider was there a striking or statistically significant change in this measure.

Visual Acuity

Exhibit 4.13 presents the before and after distributions of pre-operative visual acuity in the operative eye at the three providers. At Site 1, the rough distribution of pre-operative acuity improved, but the difference in means was not statistically significant. At Site 3, the distribution became slightly more compact - fewer patients had visual acuity of 20/80 or worse, more had visual acuity between 20/70 and 20/50, fewer had visual acuity better than 20/40 - again, with no difference in means. At Site 4, there were fewer patients in the worse than 20/200, 20/150-20/80, and 20/70-20/50 category and more in the 20/40 and better category. Here, the difference in mean acuity was statistically significant and consistent with risk selection.

Cataract Type

Information on patients' cataract type is depicted in Exhibit 4.14. At Site 1, the percentage of patients with nuclear cataracts remained roughly constant between baseline and demonstration, the percentage with PSC cataracts declined and the percentage with cortical cataracts increased. At Site 3, a higher percentage of patients had nuclear cataracts and a higher percentage had cortical cataracts while the percentage with PSC cataracts remained approximately steady. At Site 4, a higher percentage had PSC cataracts and a higher percentage had cortical cataracts with a slight decline in the percentage with nuclear cataracts. There were statistically significant changes in the distribution of patients across the

various categories of cataract type as well. Recall that there is no direct relationship between type of cataract and cost or risk of cataract surgery.

Significant Pre-Operative Ocular Pathologies

The next exhibit summarizes pre-operative comorbidities. At Site 1, providers reported that, in the demonstration period, 81.5 percent of patients had "no ocular disease other than cataract" as opposed to 75.2 percent in the baseline period; in particular, 5.6 percent of patients had glaucoma in the demonstration period as opposed to 11.6 percent in the baseline period. These statistically significant differences are consistent with this provider serving patients who were lower risk during the demonstration and/or with recall bias.

At Site 3, the percentages of patients with no other ocular disease were identical in both periods. The one statistically significant difference in pre-operative pathology was a fall in the percentage of patients with prior intraocular surgery.

At Site 4, there was a statistically significant *decrease* in the percentage of patients with no other eye disease, fueled by increases (none individually statistically significant) in several items, notably age-related macular degeneration. Note that this is the opposite of what risk selection would predict.

Pre-Operative Characteristics: Summary

At Site 1, the percentage of patients with no eye disease other than cataracts increased after the demonstration began. This is consistent with the hypothesis of risk selection under the demonstration but also with recall bias. At Site 3, there were no notable changes in checklist variables indicating pre-operative condition. At Site 4, there was actually a decrease in the percentage of patients with no eye disease other than cataracts, the opposite of what one would expect with risk selection.

Service Utilization

This next section investigates how service utilization changed during the demonstration period with three issues in mind: whether providers reduced their level of services in order to cut costs, whether they found ways to provide services more efficiently, and whether the timing of services changed so that providers would receive additional reimbursement.

Tests

The demonstration created a clear financial incentive to reduce the number of tests. In the baseline period, each test was reimbursed on an individual retrospective basis. In the demonstration period, a provider received the same fee whether the patient received two tests or twelve. Furthermore, as Exhibit 4.16 shows, there were no universal standards for tests. In the baseline period, all patients at Site 1 received B scan testing while no patients at Site 3 or Site 4 received it. At the same time, all patients at Site 3 received a dilated fundus exam while only about half of patients at Site 1 received it.

Given that there was no consensus regarding the usage of these tests, one might assume that if providers did reduce services, some of their reductions would take place in this area.[20]

However, as Exhibit 4.16 shows, this was not the case. At Site 1, there were statistically insignificant drops in the utilization of certain tests, but the one significant change was the 18 percentage point increase, from 53 percent to 71 percent in the usage of the dilated fundus exam. At Site 3, again, there were statistically insignificant drops in the utilization of certain tests but, again, the statistically significant changes were *increases* in the use of four tests (B scan, dilated fundus exam, keratometry, and visual field assessment.) Also at Site 4, there were four significant increases (namely glare testing, contrast sensitivity testing, assessment of potential acuity, and specular microscopy) and no significant decreases.

If providers had felt pressure to cut, this would have been a natural place. Although it is not possible to observe what would have occurred in the absence of the demonstration, the fact that the use of tests increased at all providers suggests that services were not cut as a result of the demonstration's changed incentives. This may also say something about the modest discounts achieved by the demonstration.

Operative Procedures

Information on operative procedures appears in Exhibit 4.17. Site 1 used phacoemulsification with continuous tear capsulotomy and a standard posterior chamber IOL almost exclusively in both periods. Site 3 underwent a gradual increase in the use of phacoemulsification (from 57.3 percent to 61.8 percent), a similar increase in the use of the continuous tear capsulotomy (from 50.6 percent to 60.6 percent), and maintained a constant percentage of patients receiving the standard PC IOL (92.7). At Site 4, there were dramatic changes. The percentage of patients undergoing phacoemulsification jumped from 9.8 percent to 56.0 percent, the percentage with continuous tear capsulotomies increased from 63.9 percent to 97.6 percent, and while at baseline only 8.8 percent of patients received the foldable IOL, in the demonstration period 52.8 percent received it. Note that the foldable IOL is a more expensive choice contravening the idea that providers would limit services in order to reduce costs during the demonstration.

Although these dramatic changes occurred at the same time as the demonstration, they were probably the results of secular changes in ophthalmologic practice over this period rather than direct results of the demonstration.

IOL Standardization

Like tests, the intra-ocular lens itself was an item, formerly paid separately, that was rolled into the cataracts bundle. (Of course, unlike tests, every patient clearly needs one and only one IOL.) Again, at affected providers, the change in payment offered an incentive for change in practice. Furthermore, there were probably opportunities for change, specifically choosing lower cost products and negotiating volume discounts with manufacturers.

---

20 Some tests (for example glare testing) may actually be used in order to justify cataract surgery at higher levels of Snellen acuity and therefore to increase surgical volume. However, our study design does not permit us to address this issue.

Exhibit 4.18 illustrates the fact that both Site 1 and Site 3 did increase the percentage of IOLs that came from their leading manufacturer; in the demonstration period, each clearly had a single primary supplier.

Site 1 had the same leading manufacturer, Iolab, in both the baseline and demonstration periods. However, in the demonstration period, this provider introduced a second major model (defined, for the purposes of this discussion, as a model used by more than 15 percent of patients) from Iolab, leading that manufacturer to have 85.5 percent of Site 1's total business, up from 68.2 percent in the baseline period.

Site 3 had three major models at baseline, two from Alcon and one from Storz. During the demonstration, it continued to use the two major models from Alcon but effectively phased out the model from Storz and replaced it with a third model from Alcon. As a result, in the demonstration period, Alcon had 93.8 percent of Site 3's business, as opposed to 51.7 percent at baseline. The fact that *different* manufacturers became dominant at Site 1 and Site 3 supports the interpretation that this did represent providers' decisions to buy in bulk from one manufacturer rather than one manufacturer coming to dominate the industry.

At Site 4, the leading manufacturer changed between baseline and demonstration as did the leading model. This probably reflected the dramatic increase in the percentage of this provider's patients receiving foldable PC IOLs, a practice decision rather than a purchasing decision.

Post-Operative Visits

In the baseline period, the carrier policy for Site 1 was to include all post-operative care within 120 days of surgery in the surgeon's fee. For Site 3, the policy was to include care within 28 days. Site 4's carrier had no general policy but 8 percent of episodes included at least one separately paid visit within 90 days of surgery.[21] In the demonstration period, the bundled payment included post-operative care within 120 days of surgery at all providers. One might expect that this change would reduce the number of visits, especially in the period between day 29 and day 120 at Site 3.

Total Visits

Exhibit 4.19 shows the number of post-operative visits between day 0 and day 120 at each provider. At Site 1 and Site 3, there were a statistically insignificant decrease and increase respectively; at Site 4, the mean number of visits actually rose.

At the first two providers, almost all post-operative visits were physician visits in both the baseline and the demonstration period; these providers' visit patterns remained fairly constant. At Site 4, at baseline, the median patient received three physician visits and no optometrist visits; however, even at baseline, optometrists had a presence at this provider; the mean number of optometrist visits was .56. In the demonstration period, however, the median patient at Site 4 received two physician visits and

21 6.9 percent of episodes in Ohio and 59.5 percent of episodes in Texas included at least one separately paid visit within 90 days. Information on carrier policies is from 1988 and comes from a HCFA phone survey. Percents of episodes with separately paid visits are derived from BMAD data before 1990.

two optometrist visits; the means were 2.55 physician visits and 1.66 optometrist visits with both changes highly statistically significant.[22]

Visits By Month

Exhibit 4.19 also shows the average numbers of visits by month at each provider. At Site 1, where incentives had not changed, there was a statistically significant decrease in visits during the fourth month. ("During the fourth month" in this context means between 90 and 120 days after surgery.)

At Site 3, where there was an incentive to reduce visits in months 2 through 4, mean visits in each of those months actually rose, with the increase in month 2 statistically significant.[23] Moreover, there was a statistically significant decrease in mean visits during month 1. This is the opposite of what would be expected if physicians were gaming the payment system.

At Site 4, where there were no clear changes in incentives, the mean total number of visits rose in month 1, probably as a byproduct of optometric comanagement.

YAG

Normally, Medicare pays about $500 for a patient's nd:YAG capsulotomy. Under the terms of the demonstration though, providers received no marginal payment if YAG was performed in the first 120 days following surgery, but they received the full payment if YAG was postponed until day 121 or later.

As might be expected, YAG rates during the first 120 days fell at all three demonstration providers between the baseline and demonstration period. At Site 1 and Site 3, these decreases were significant at the 5 percent level; at Site 4, at the 10 percent level. This evidence supports the conjecture that physicians may have altered the timing of care in order to increase reimbursement. However, as noted below, due to limitations in the scope of the evaluation, we were not able to test this hypothesis.

In order to put this finding into perspective, it would be useful to know the rate of YAG capsulotomy over the subsequent time period (between day 121 and day 365, for example). Then, we could establish whether the observed change during the first four months represents changed timing, as hypothesized, or an actual reduction in care. It would also be useful to know if the rates of YAG within 120 days of surgery were falling among the general population of Medicare beneficiaries during the demonstration period. Unfortunately, data limitations prevented us from exploring this issue.[24]

---

22 The fact that the bundled payment demonstration extended the window of time during which follow-up care was paid prospectively was conducive to cooperatiaon with optometrists. From a clinical perspective, the long window made it likely that the patient would no longer need the surgeon's expertise in the latter part of the window. From a financial perspective, the longer window made it less likely that the patient would require additional fee-for-service visits outside the window and hence may have made surgeons more willing to "relinquish" the care of the patients to optometrists. It is surprising that more providers did not make serious attempts to implement optometric comanagement.

23 This may be the result of higher complication rates discussed below.

24 Abt's original evaluation plan contained an analysis of Medicare claims to answer this among other questions.

Service Utilization: Summary

This section has explored the demonstration's effects on service utilization. There is no evidence that services were reduced. Among all three providers, there was a significant increase in the use of diagnostic tests between baseline and demonstration. There was a dramatic change in practice at Site 4 during the demonstration period that included increased use of the foldable PC IOL (a more expensive item.) Finally, the number of visits remained constant at Site 1 and Site 3 and rose at Site 4, probably because increased use of optometric comanagement was part of that provider's change in practice.

There is some evidence that standardization occurred which might indicate increased efficiency. Specifically, two providers increased the percentage of their IOLs that came from a single manufacturer.

Finally, there is mixed evidence regarding providers altering the timing of services to maximize revenue. At Site 3, the month-by-month profile of visits did not change in accordance with incentives. However, every provider decreased the percentage of its patients that received YAG within four months of surgery when the demonstration created a powerful incentive to delay that procedure beyond day 120.

Clinical Outcomes

The previous section showed that levels of certain measurable services did not decline during the demonstration.[25] Part of our interest in levels of service stems from an interest in cost control (cost control for the Medicare program ultimately depends on cost control by the providers) and part from an interest in the quality of care - changes in service sometimes, though not always, indicate changes in the quality of care. Another way to explore the quality of care is via clinical outcomes, the subject of the next section.

Rates of Complications

Intra-Operative Complications

Exhibit 4.21 tabulates the rates of complications for the three sites pooled in the baseline and demonstration periods.[26] Reported rates of all intra-operative complication either increased or remained constant between the baseline and demonstration period. However, none of the individual changes nor the change in the summary measure were satistically significant.

Post-Operative Complications

Findings for reported rates of post-operative complications, shown in Exhibit 4.22, were quite similar. Rates of all post-operative complications, save elevated IOP, increased between the baseline and PPO period. However, none of the increases except the increase in iritis was statistically significant.

---

25 Our assumption is that declines in YAG within 120 days represent procedures that are postponed not eliminated.

26 Sites were pooled to ensure anonymity given the sensitive nature of this information.

The demonstration effects on "any intra-operative event" and "any post-operative event" estimated via regression analysis (see Appendix D) were similarly positive but statistically insignificant.

Visual Acuity

Post-Operative Level of Visual Acuity

At all providers in both time periods, median post-operative visual acuity was 20/25 (.8) and mean visual acuity was between 20/25 (.8) and 20/30 (.67). At Site 1, mean visual acuity increased from .76 at baseline and to .77 during the demonstration; this change was not statistically significant. At Site 3, mean visual acuity was .75 in both periods. Finally, at Site 4, this measure was .71 at baseline and .75 during the demonstration; this did represent a statistically significant improvement.

The change in post-operative visual acuity at Site 4 remained statistically significant in a regression that controlled for patients' pre-operative characteristics, including categorical measures of pre-operative visual acuity.

Change in Snellen Lines

At all three providers, average *improvement* in visual acuity in the operative eye (defined as change in Snellen lines) declined from the baseline to the demonstration period but these declines were not statistically significant. This does corroborate the finding above because both pre-operative and post-operative visual acuity increased at Site 4.

With controls for pre-operative characteristics, Site 4 showed a statistically significant improvement in this measure between baseline and demonstration.

Clinical Outcomes: Summary

Documented rates of both intra-operative and post-operative events increased between the baseline and demonstration periods. However, these increases were generally not statistically significant and were consistent either with recall bias or with demonstration effects. At Site 4, both the level of post-operative visual acuity and the change in acuity (adjusted for pre-operative characterstics) improved. These changes in acuity may be the result of the changes in practice Site 4 made during the demonstration, which might also have occurred in its absence. Thus, on balance, there is no impact on outcomes that can be directly attributed to the demonstration.

4.5 Summary of Findings from Analysis of Clinical Data

This section has investigated the impact of the demonstration on clinical measures. Its main findings are:

- At baseline, patients of demonstration providers were fairly typical in terms of clinical measures.

- During the demonstration, one provider's patients exhibited more favorable pre-operative characteristics than had been the case at baseline; this could have been the result of risk

selection or of biases in the data. The other two providers patients exhibited roughly similar pre-operative characteristics.

- No provider curtailed services during the demonstration.

- Two providers increased the percentage of their IOLs that came from their leading manufacturer between baseline and demonstration suggesting an increase in the efficiency of service provision.

- All providers decreased the percentage of their patients that received nd:YAG capsulotomies within 120 days of surgery. We hypothesize that this represented delaying (not eliminating) YAG in order to receive additional reimbursement for the procedure. However, as noted above, data limitations did not permit us to test this hypothesis.

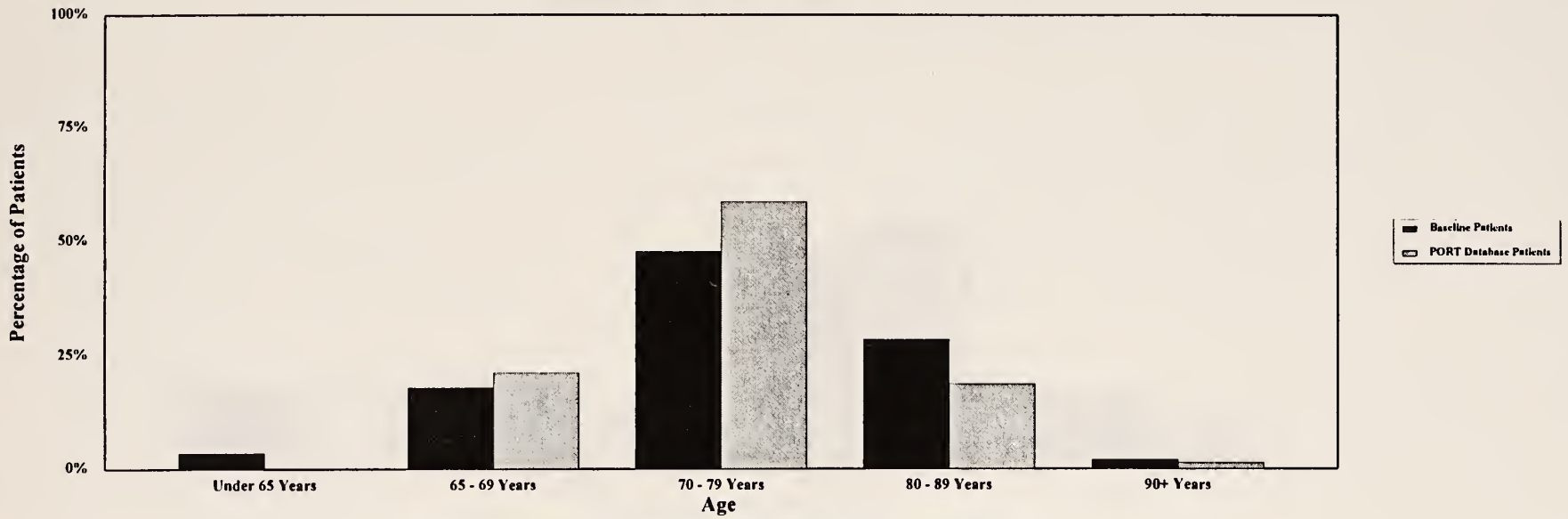
- No change in clinical outcomes could be attributed to the demonstration.

Exhibit 4.1

Baseline and Demonstration Response Rates By Provider By Year

	Site 1	Site 3	Site 4	All Providers		
	Reponse Rate	Response Rate	Response Rate	Number in Sample	Number Returned	Response Rate
Baseline 91-92	81%	68%	82%	673	512	76%
Demo 93-96	84%	83%	90%	4,152	3,583	86%

Cataracts Exhibit 4.2: Distribution of Baseline and PORT Database Patients by Age



SOURCE: Data compiled by Abt Associates from PatientChecklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992 and from clinical data forms completed by ophthalmologists participating in the PORT.

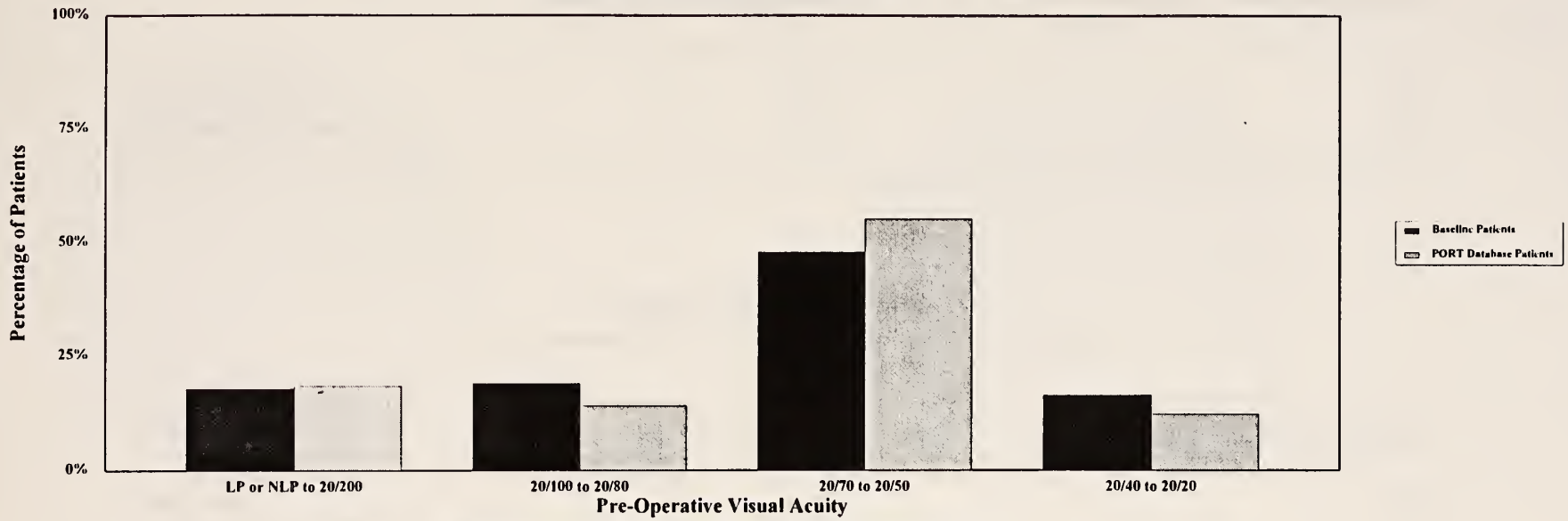
Cataracts Patients by Age -- Frequencies and Percentages

Age Distribution	BASELINE: Number of Baseline Patients (N=512)	BASELINE: Percentage of Baseline Patients	PORT DATABASE: Number of PORT Database Patients (N=598)	PORT DATABASE: Percentage of PORT Database Patients
Age Not Reported/Missing Information	1	0.2%	0	0.0%
Under 65 Years	18	3.5%	0	0.0%
65 - 69 Years	92	18.0%	127	21.2%
70 - 79 Years	245	47.9%	351	58.7%
80 - 89 Years	146	28.5%	112	18.7%
90+ Years	10	2.0%	8	1.3%

Median and Mean Ages

	Baseline Patients	PORT Database Patients	
Median Age	76 years	74 years	
Mean Age	75.55 years	74.57 years	t test *

Cataracts Exhibit 4.3: Distribution of Baseline and PORT Database Patients by Pre-Operative Visual Acuity



SOURCE: Data compiled by Abt Associates from Patient Checklists submitted by demonstration providers and from clinical data forms completed by ophthalmologists participating in the PORT.

Cataracts Patients by Pre-Operative Visual Acuity -- Frequencies and Percentages

	BASELINE		PORT DATABASE	
Pre-Operative Acuity Distribution	Number of Baseline Patients (N=512)	Percentage of Baseline Patients	Number of PORT Database Patients (N=598)	Percentage of PORT Database Patients
LP or NLP to 20/200	91	17.8%	110	18.4%
20/100 to 20/80	97	18.9%	84	14.1%
20/70 to 20/50	245	47.9%	330	55.3%
20/40 to 20/20	84	16.4%	73	12.2%
Missing Data	0	0.0%	0	0.0%

T Test on Pre-Operative Visual Acuity of 20/40+ ** (for baseline and PORT)

Median and Mean Pre-Operative Acuity

	Baseline Patients	PORT Database Patients	
Median Pre-Operative Acuity	20/60	20/60	
Mean Pre-Operative Acuity	.316*	.316*	t test NS

*NOTE: Mean pre-operative acuity between 20/60 (.33) and 20/70 (.28)

Exhibit 4.4: Baseline versus PORT Database, Cataract Type

	BASELINE		PORT DATABASE		
	Number of Baseline Patients (N=512)	Percentage of Baseline Patients	Number of PORT Database Patients (N=598)	Percentage of PORT Database Patients	T Test Result
Any Nuclear Cataract	437	85.4%	505	84.4%	NS
Any Cortical Cataract	118	23.0%	186	31.1%	***
Any Posterior Subcapsular Cataract	75	14.6%	148	24.7%	***

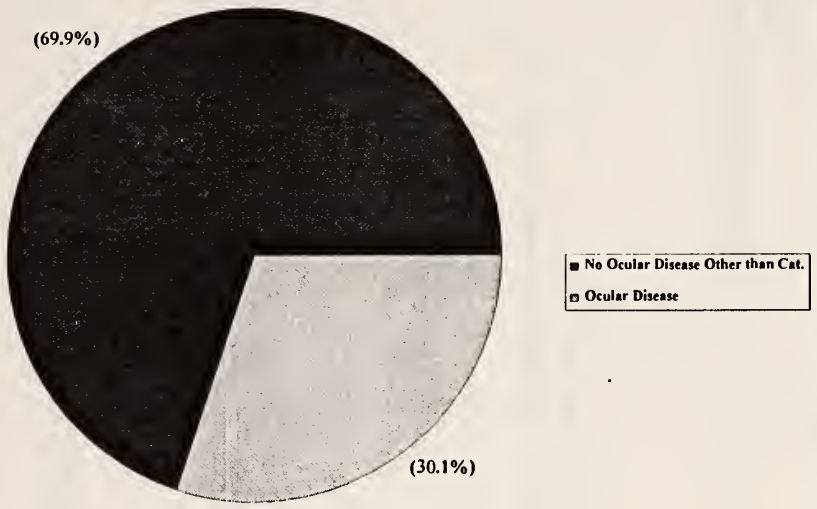
Baseline and PORT Patients by Cataract Type -- Frequencies and Percentages

	BASELINE		PORT DATABASE	
Type of Cataract	Number of Baseline Patients (N=512)	Percentage of Baseline Patients	Number of PORT Database Patients (N=598)	Percentage of PORT Database Patients
Nuclear Alone	336	65.6%	307	51.3%
Nuclear and Posterior Subcapsular	40	7.8%	88	14.7%
Nuclear and Cortical	43	8.4%	78	13.0%
Nuclear, Posterior Subcapsular, and Cortical	8	1.6%	4	0.7%
Cortical Alone	7	1.4%	23	3.8%
Cortical and Posterior Subcapsular	7	1.4%	15	2.5%
Posterior Subcapsular Alone	53	10.4%	51	8.5%
None	18	3.5%	32	5.4%
Chi Square Test				***

SOURCE (baseline v PORT Database) Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from late 1991 and 1992 and from clinical data forms completed by ophthalmologists participating in the PORT

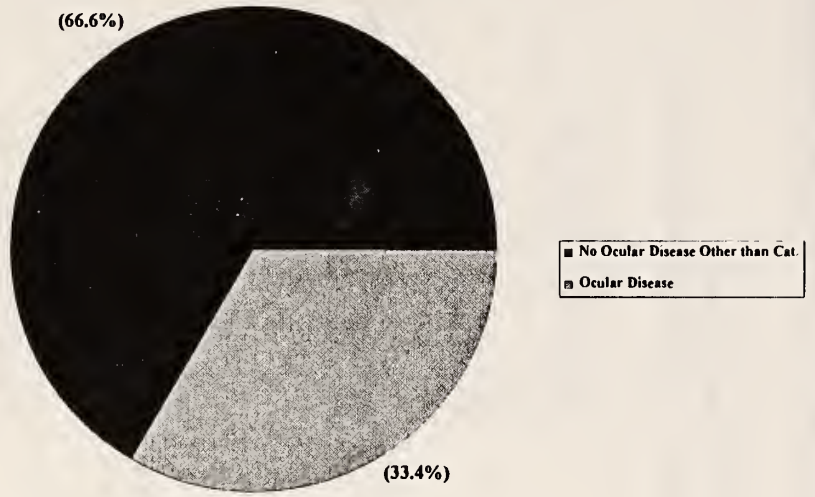
NOTE: The four categories for the Chi Square Test were "nuclear alone", "nuclear and PSC (and cortical)", "nuclear and cortical", and "no nuclear"

Cataracts Exhibit 4.5a: Distribution of Baseline Patients by Pre-Operative Comorbidity



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.5b: Distribution of PORT Database Patients by Pre-Operative Comorbidity



SOURCE: Data compiled from clinical data forms completed by ophthalmologists participating in the PORT.

Cataracts Patients by Pre-Operative Comorbidity -- Frequencies and Percentages

	BASELINE		PORT DATABASE		
Pre-Operative Comorbidity	Number of Baseline Patients With Indicated Pre-Operative Comorbidity (N=512)	Percentage of Baseline Patients With Indicated Pre-Operative Comorbidity	Number of PORT Patients With Indicated Pre-Operative Comorbidity (N=598)	Percentage of PORT Database Patients With Indicated Pre-Operative Comorbidity	T Test Result
No Ocular Disease Other than Cataract	358	69.9%	398	66.6%	NS
Amblyopia	5	1.0%	10	1.7%	NS
Age-Related Macular Degeneration	59	11.5%	63	10.5%	NS
Glaucoma	49	9.6%	61	10.2%	NS
Other Optic Nerve Disease	0	0.0%	7	1.2%	**
Chronic Uveitis or Keratitis	0	0.0%	3	0.5%	NS
Previous Retinal Detachment	4	0.8%	7	1.2%	NS
Diabetic Retinopathy	13	2.5%	18	3.0%	NS
History of Prior Intraocular Surgery	4	0.8%	13	2.2%	*

Exhibit 4.6: Baseline versus PORT Database, Operative Procedures

Baseline and PORT Patients by Extraction Technique -- Frequencies and Percentages

Extraction Technique	BASELINE Number of Baseline Patients (N=512)	BASELINE Percentage of Baseline Patients	PORT DATABASE Number of PORT Database Patients (N=598)	PORT DATABASE Percentage of PORT Database Patients
ECCE	259	50.6%	197	32.9%
Phaco.	251	49.0%	384	64.2%
Converted	0	0.0%	8	1.3%
Other / Aborted	2	0.4%	9	1.5%
Missing Data	0	0.0%	0	0.0%

T Test on Percent Phacoemulsification Extraction *** (for baseline and PORT)

NOTE: PORT combines "extracapsular (phaco.)" and "endocapsular phaco." Baseline combines "Extracapsular with iris plane/anterior chamber phaco." and "Posterior chamber phaco".

Baseline and PORT Patients by Capsulotomy Technique -- Frequencies and Percentages

Capsulotomy Technique	BASELINE Number of Baseline Patients (N=512)	BASELINE Percentage of Baseline Patients	PORT DATABASE Number of PORT Database Patients (N=598)	PORT DATABASE Percentage of PORT Database Patients
Can Opener	160	31.3%	197	32.9%
Scissors	1	0.2%	1	0.2%
Continuous Tear	348	68.0%	379	63.4%
Missing Data	3	0.6%	21	3.5%

T Test on Percent Continuous Tear NS (for baseline and PORT)

Baseline and PORT Patients by IOL Implant Technique -- Frequencies and Percentages

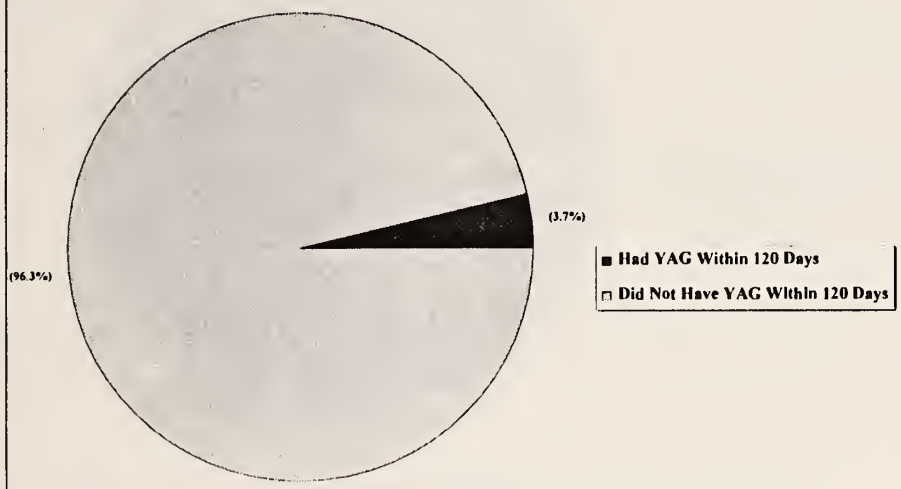
Implant Technique	BASELINE Number of Baseline Patients (N=512)	BASELINE Percentage of Baseline Patients	PORT DATABASE Number of PORT Database Patients (N=598)	PORT DATABASE Percentage of PORT Database Patients
Standard PC IOL	480	93.8%	548	91.6%
Foldable PC IOL	20	3.7%	39	6.5%
Ant. Chamber IOL	12	2.3%	6	1.0%
Missing Data/Other	0	0.2%	5	0.8%

T Test on Percent Standard PC IOL not significant (for baseline and PORT)

NOTE: PORT combines "Standard posterior chamber in bag" and "Standard posterior chamber in sulcus".

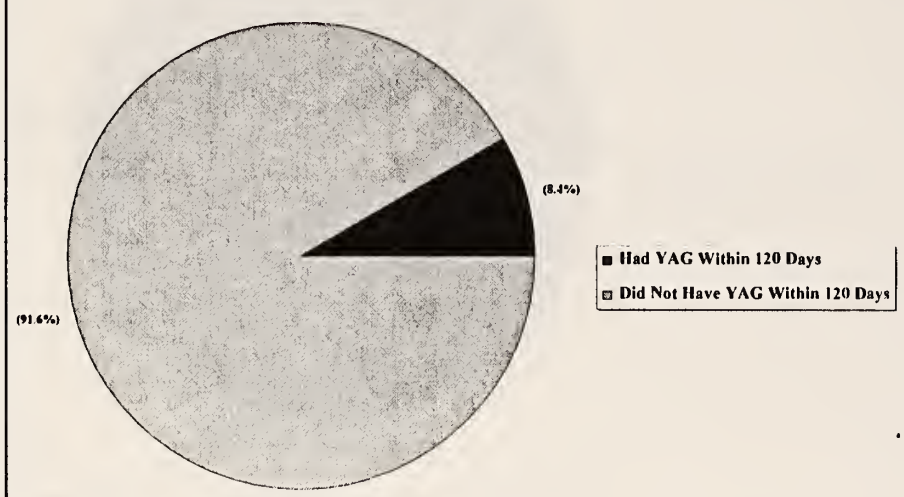
SOURCE (baseline v. PORT Database): Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from late 1991 and 1992 and from clinical data forms completed by ophthalmologists participating in the PORT.

Cataracts Exhibit 4.7a: Distribution of Baseline Patients Who Had a YAG Capsulotomy Within 120 Days of Surgery



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.7b: Distribution of PORT Database Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery



SOURCE: Data compiled from clinical data forms completed by ophthalmologists participating in the PORT.

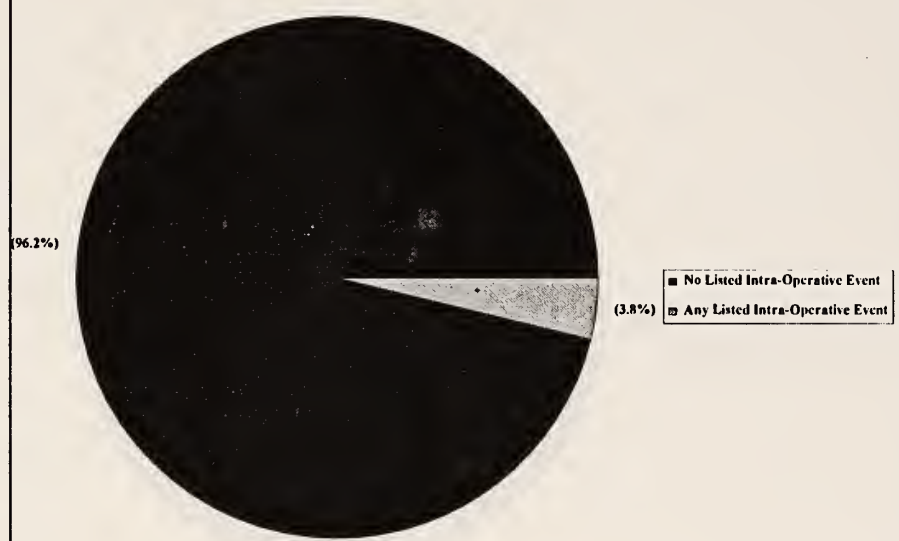
Cataracts Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Frequencies and Percentages

	BASELINE		PORT DATABASE		
YAG Capsulotomy Within 120 Days After Surgery	Number of Baseline Patients (N=512)	Percentage of Baseline Patients	Number of PORT Database Patients (N=598)	Percentage of PORT Database Patients	
Yes	19	3.7%	50	8.4%	t test pct. "YES" ***
No	493	96.3%	548	91.6%	

Cataracts Exhibit 4.8a: Distribution of Baseline Patients by Intra-Operative Event

SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.8b: Distribution of PORT Database Patients by Intra-Operative Event

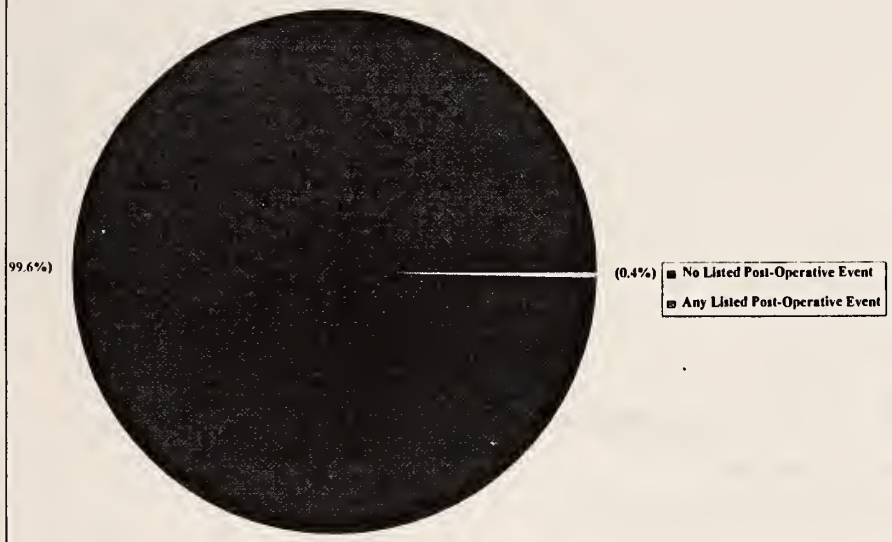


SOURCE: Data compiled from clinical data forms ophthalmologists participating in the PORT.

Cataracts Patients by Intra-Operative Event -- Frequencies and Percentages

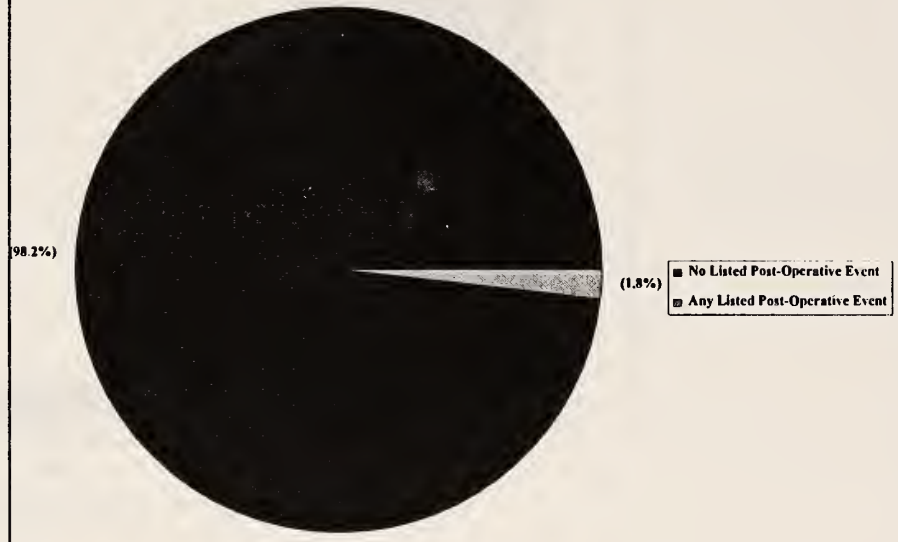
	BASELINE		PORT DATABASE		
Intra-Operative Event	Number of Baseline Patients Experiencing Indicated Intra-Operative Event (N=512)	Percentage of Baseline Patients Experiencing Indicated Intra-Operative Event	Number of PORT Patients Experiencing Indicated Intra-Operative Event (N=598)	Percentage of PORT Database Patients Experiencing Indicated Intra-Operative Event	T Test Result
No Listed Intra-Operative Event	501	97.9%	575	96.2%	NS
Posterior Capsular/ Zonal Rupture	6	1.2%	12	2.0%	NS
Vitreous Loss	6	1.2%	9	1.5%	NS
Posterior Loss of Nuclear Fragment	0	0.0%	2	0.3%	NS
Choroidal Hemorrhage	0	0.0%	1	0.2%	NS
Retrobulbar Hemorrhage	0	0.0%	1	0.2%	NS
Globe Perforation	0	0.0%	0	0.0%	NS
Anterior Hemorrhage	0	0.0%	9	1.5%	***
Any Listed Intra-Operative Event	11	2.1%	23	3.8%	NS

Cataracts Exhibit 4.9a: Distribution of Baseline Patients by Post-Operative Event



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers.

Cataracts Exhibit 4.9b: Distribution of PORT Database Patients by Post-Operative Event

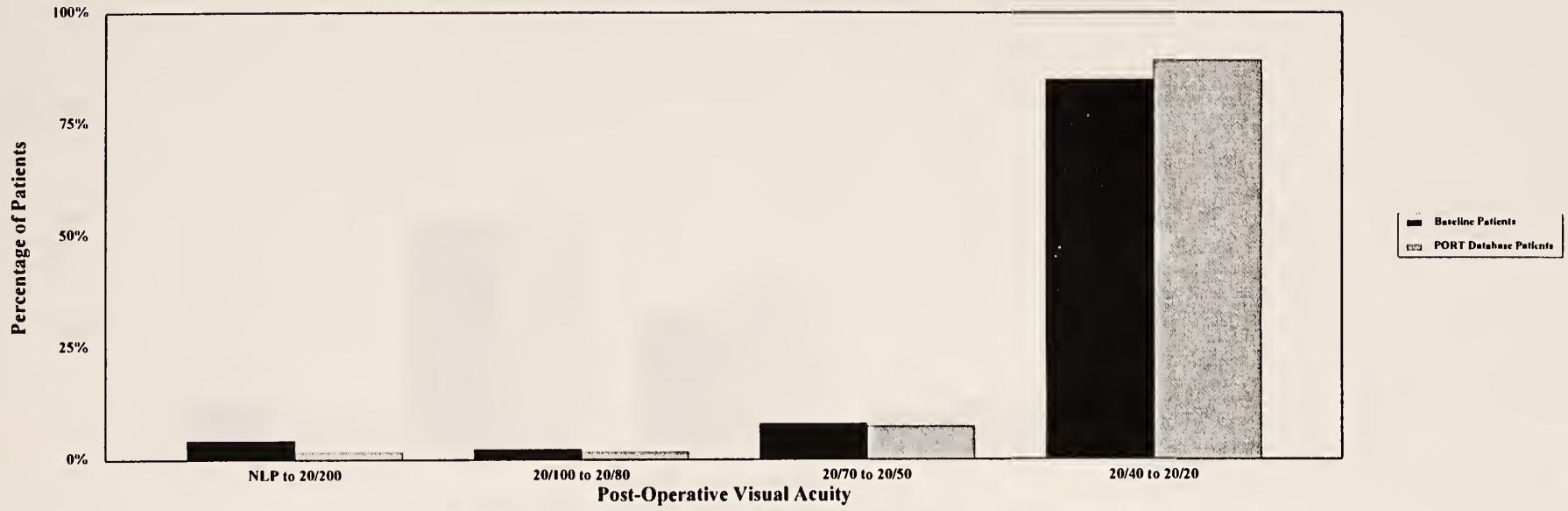


SOURCE: Data compiled from clinical data forms ophthalmologists participating in the PORT.

Cataracts Patients by Post-Operative Event -- Frequencies and Percentages

	BASELINE		PORT DATABASE		
Post-Operative Event	Number of Baseline Patients Experiencing Indicated Post-Operative Event (N=512)	Percentage of Baseline Patients Experiencing Indicated Post-Operative Event	Number of PORT Patients Experiencing Indicated Post-Operative Event (N=598)	Percentage of PORT Database Patients Experiencing Indicated Post-Operative Event	T Test Result
No Listed Post-Operative Event	510	99.6%	587	98.2%	**
Endophthalmitis	0	0.0%	0	0.0%	NS
IOL Dislocation	2	0.4%	2	0.3%	NS
Wound Leak/ Rupture	0	0.0%	9	1.5%	***
Retinal Tear/ Detachment	0	0.0%	2	0.3%	NS
Any Listed Post-Operative Event (BASED ON 4 ITEMS ABOVE)	2	0.4%	11	1.8%	**

Cataracts Exhibit 4.10: Distribution of Baseline and PORT Database Patients by Post-Operative Visual Acuity



SOURCE: Data compiled by Abt Associates from Patient Checklists submitted by demonstration providers and from clinical data forms completed by ophthalmologists participating in the PORT.

Cataracts Patients by Post-Operative Visual Acuity -- Frequencies and Percentages

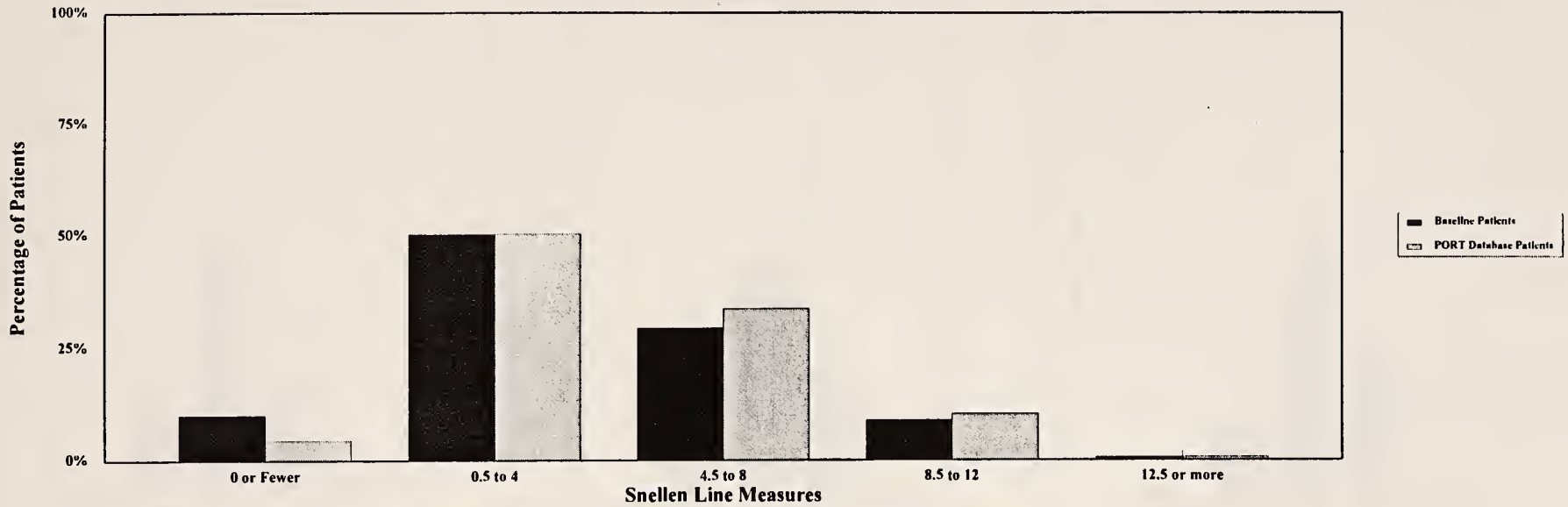
Post-Operative Acuity Distribution	BASELINE		PORT DATABASE	
	Number of Baseline Patients (N=512)	Percentage of Baseline Patients	Number of PORT Database Patients (N=598)	Percentage of PORT Database Patients
NLP to 20/200	22	4.3%	10	1.7%
20/100 to 20/80	12	2.3%	10	1.7%
20/70 to 20/50	41	8.0%	44	7.4%
20/40 to 20/20	435	85.0%	533	89.3%
Missing Data	2	0.4%	1	0.2%

Median and Mean Post-Operative Acuity

	Baseline Patients	PORT Database Patients	
Median Post-Operative Acuity	20/25	20/25	
Mean Post-Operative Acuity	.733	.785	t test ***

NOTE: Baseline and PORT Database mean post-operative visual acuities are between 20/30 (.67) and 20/25 (.80)

Cataracts Exhibit 4.11: Distribution of Baseline and PORT Database Patients by Change in Snellen Lines



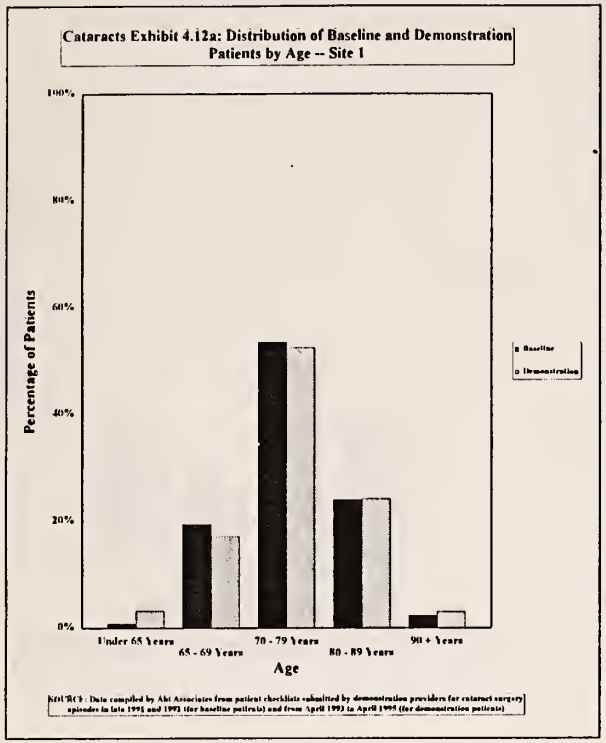
SOURCE: Data compiled by Abt Associates from PatientChecklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992 and from clinical data forms completed by ophthalmologists participating in the PORT.

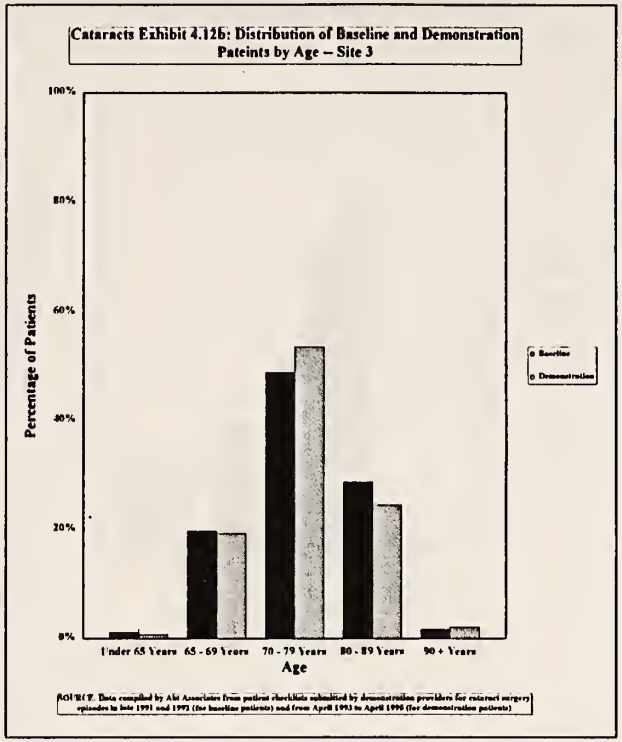
Cataracts Patients by Change in Snellen Lines -- Frequencies and Percentages

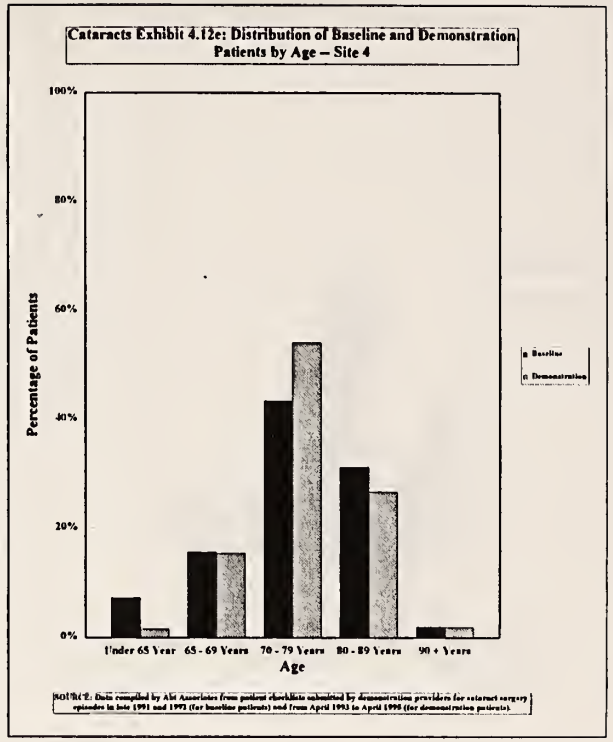
Snellen Line Measures	BASELINE		PORT DATABASE	
	Number of Baseline Patients (N=512)	Percentage of Baseline Patients	Number of PORT Database Patients (N=598)	Percentage of PORT Database Patients
0 or Fewer	52	10.2%	27	4.5%
0.5 to 4	258	50.4%	302	50.5%
4.5 to 8	151	29.5%	202	33.8%
8.5 to 12	46	9.0%	62	10.4%
12.5 or more	3	0.6%	4	0.7%
Missing Data	2	0.4%	1	0.2%

Median and Mean Change in Snellen Lines

	Baseline Patients	PORT Database Patients	
Median Snellen Line Change	4	4	
Mean Snellen Line Change	4.08	4.64	t test ***





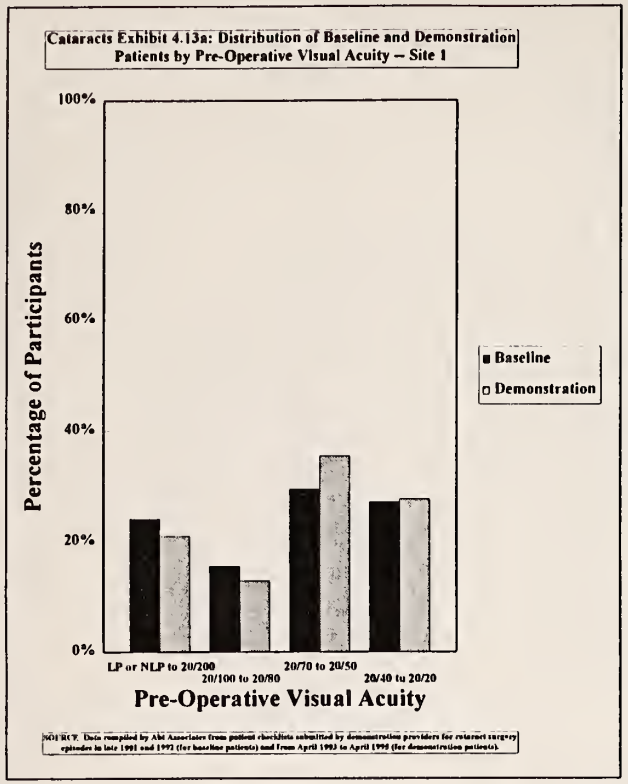


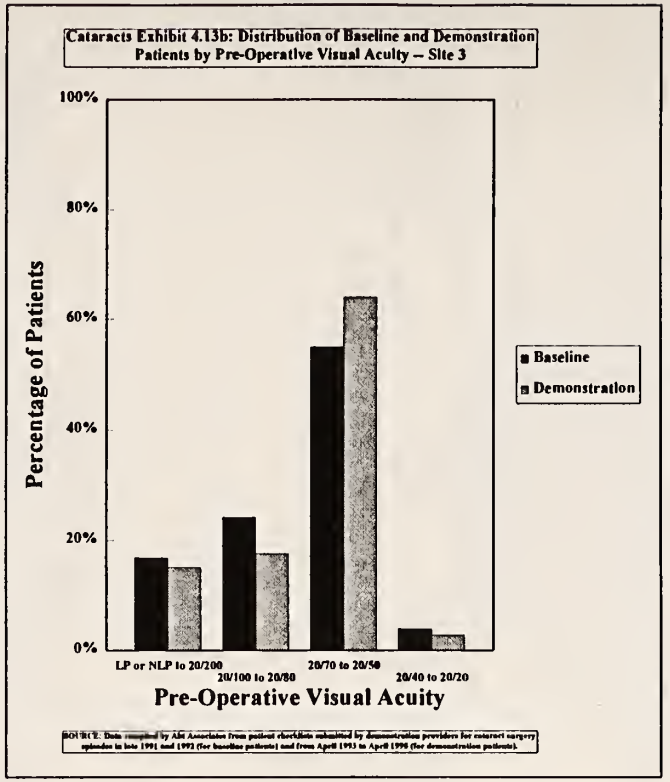
Cataracts Patients by Age -- Frequencies and Percentages

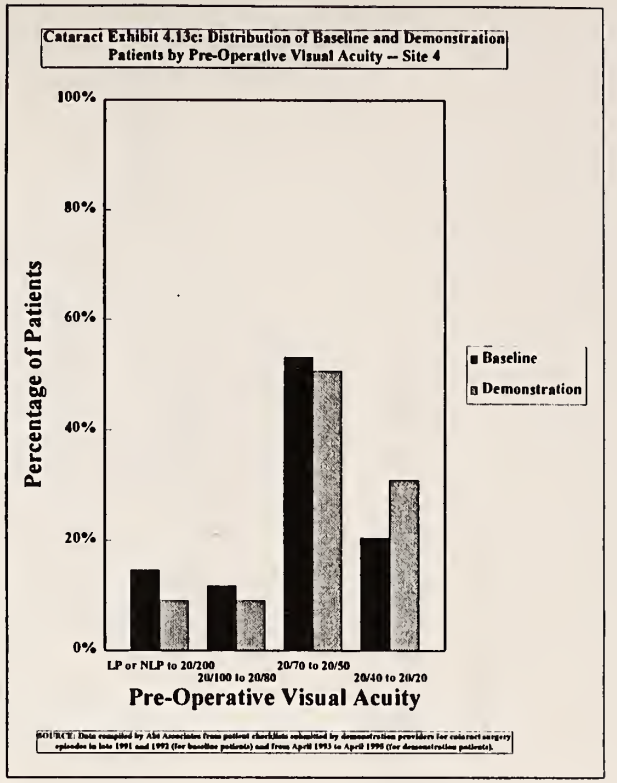
Age Distribution	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
Age Not Reported/Missing Information	0.0%	0.0%	0.0%	0.1%	0.5%	0.2%
Under 65 Years	0.8%	3.3%	1.1%	0.7%	7.3%	1.6%
65 - 69 Years	19.4%	17.1%	19.7%	19.2%	15.6%	15.4%
70 - 79 Years	53.5%	52.5%	48.8%	53.5%	43.4%	54.2%
80 - 89 Years	24.0%	24.2%	28.7%	24.4%	31.2%	26.7%
90 + Years	2.3%	3.1%	1.7%	2.1%	2.0%	1.9%

Median and Mean Age

	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Age	77 years	75 years		75 years	75 years		75 years	76 years	
Mean Age	76.03 years	76.01 years	t test *	75.41 years	75.32 years	t test NS	75.37 years	75.91 years	t test NS







Cataracts Patients by Pre-Operative Visual Acuity -- Frequencies and Percentages

Pre-Operative Acuity Distribution	Site 1 Percentage of Baseline Patients	Site 1 Percentage of Demo. Patients	Site 3 Percentage of Baseline Patients	Site 3 Percentage of Demo. Patients	Site 4 Percentage of Baseline Patients	Site 4 Percentage of Demo. Patients
LP or NLP to 20/200	24.0%	20.9%	16.8%	15.1%	14.6%	9.1%
20/100 to 20/80	15.5%	12.8%	24.2%	17.6%	11.7%	9.1%
20/70 to 20/50	29.5%	35.4%	55.1%	64.1%	53.2%	50.7%
20/40 to 20/20	27.1%	27.7%	3.9%	2.8%	20.5%	31.0%
Missing Data	3.9%	3.2%	0.0%	0.4%	0.0%	0.1%

T Test on Pre-Operative Visual Acuity of 20/40+ not significant for Site 1 (baseline and demonstration).
T Test on Pre-Operative Visual Acuity of 20/40+ not significant for Site 3 (baseline and demonstration)
T Test on Pre-Operative Visual Acuity of 20/40+ ** for Site 4 (Baseline and demonstration)

Median and Mean Pre-Operative Acuity

	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Pre-Operative Acuity	20/70	20/60		20/70	20/70		20/60	20/60	
Mean Pre-Operative Acuity	.331	.339	t test NS	.30	.29	t test NS	.34	.38	t test **

NOTE: Site 1 mean pre-operative visual acuity roughly 20/60 (.333) in both periods.
NOTE: Site 3 mean pre-operative visual acuity roughly 20/70 (.29) in both periods.
NOTE: Site 4 mean pre-operative visual acuity roughly 20/60 (.333) in both periods.

Exhibit 4.14: Baseline and Demonstration Patients by Cataract Type Frequencies and Percentages

Type of Cataract	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	T Test Result
Any Nuclear Cataract	90.7%	91.3%	NS
Any Cortical Cataract	7.8%	16.6%	***
Any Posterior Subcapsular Cataract	20.9%	10.7%	***

Type of Cataract	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients
Nuclear Alone	69.8%	69.3%
Nuclear and Posterior Subcapsular	14.0%	7.4%
Nuclear and Cortical	6.2%	14.4%
Nuclear, Posterior Subcapsular, and Cortical	0.8%	0.3%
Cortical Alone	0.0%	1.4%
Cortical and Posterior Subcapsular	5.4%	2.6%
Posterior Subcapsular Alone	0.8%	0.5%
None	3.1%	4.1%
Chi Square Test (4 Categories)		*

Type of Cataract	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	T Test Result
Any Nuclear Cataract	72.5%	87.1%	***
Any Cortical Cataract	32.0%	38.2%	NS
Any Posterior Subcapsular Cataract	40.4%	40.4%	NS

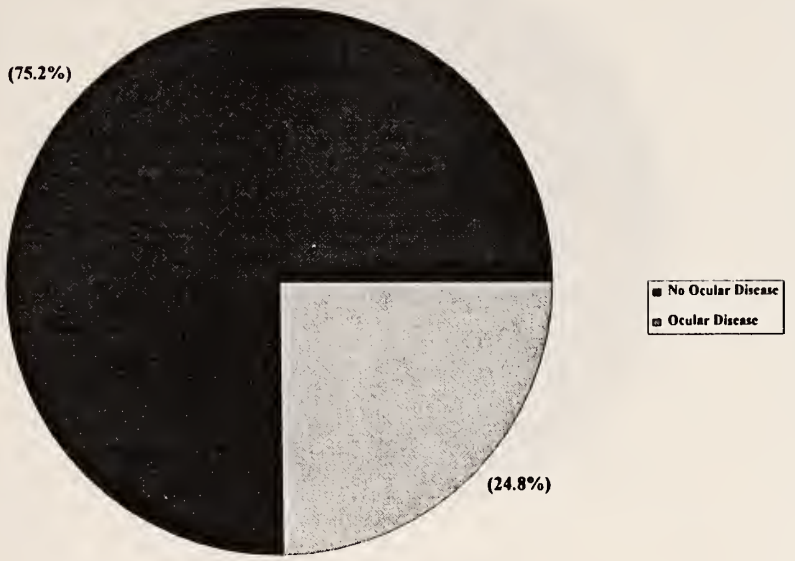
Type of Cataract	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients
Nuclear Alone	38.8%	47.9%
Nuclear and Posterior Subcapsular	7.9%	5.1%
Nuclear and Cortical	16.3%	9.9%
Nuclear, Posterior Subcapsular, and Cortical	9.6%	0.2%
Cortical Alone	2.8%	1.0%
Cortical and Posterior Subcapsular	19.7%	1.8%
Posterior Subcapsular Alone	3.4%	0.4%
None	1.7%	2.9%
Chi Square Test (4 Categories)		***

Type of Cataract	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients	T Test Result
Any Nuclear Cataract	93.2%	91.7%	NS
Any Cortical Cataract	9.3%	18.7%	***
Any Posterior Subcapsular Cataract	3.9%	6.8%	NS

Type of Cataract	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
Nuclear Alone	86.3%	73.7%
Nuclear and Posterior Subcapsular	3.9%	13.3%
Nuclear and Cortical	2.9%	4.5%
Nuclear, Posterior Subcapsular, and Cortical	0.0%	0.2%
Cortical Alone	1.0%	1.7%
Cortical and Posterior Subcapsular	5.4%	4.8%
Posterior Subcapsular Alone	0.0%	0.4%
None	0.5%	1.4%
Chi Square Test (4 Categories)		***

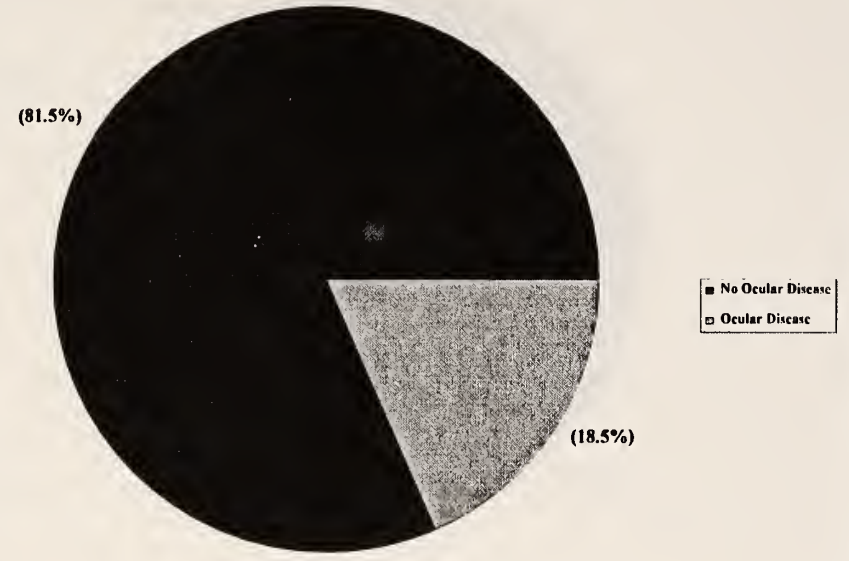
SOURCE (baseline v. demonstration): Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from late 1991 to 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.15a: Distribution of Baseline Patients by Pre-Operative Comorbidity -- Site 1



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.15b: Distribution of Demo. Patients by Pre-Operative Comorbidity -- Site 1

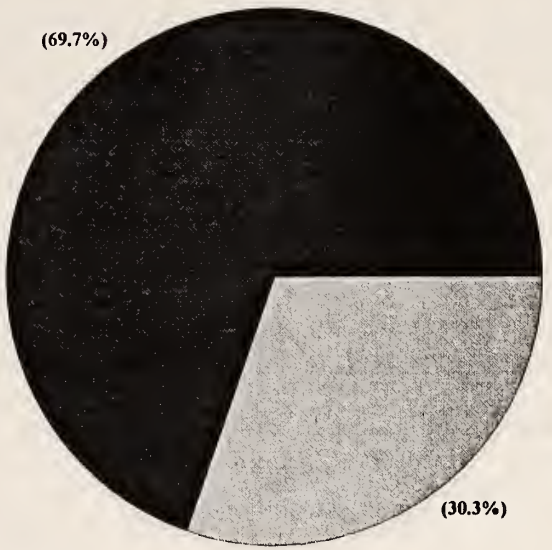


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Site 1 Patients by Pre-Operative Comorbidity -- Frequencies and Percentages

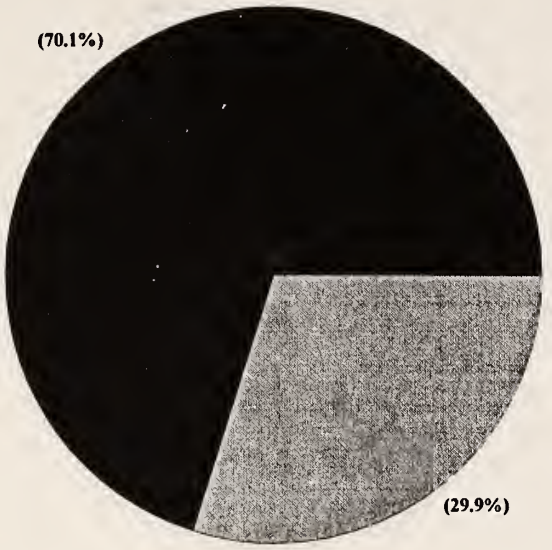
Pre-Operative Comorbidity	BASELINE PATIENTS – SITE 1: Percentage of Baseline Patients With Indicated Pre-Operative Comorbidity	DEMONSTRATION PATIENTS – SITE 1: Percentage of Demonstration Patients With Indicated Pre-Operative Comorbidity	T Test Result
No Ocular Disease Other than Cataract	75.2%	81.5%	*
Amblyopia	0.8%	2.1%	NS
Age-Related Macular Degeneration	6.2%	5.8%	NS
Glaucoma	11.6%	5.6%	**
Other Optic Nerve Disease	0.0%	0.4%	NS
Corneal Dystrophy/Opacification	0.8%	0.8%	NS
Chronic Uveitis or Keratitis	0.0%	0.1%	NS
Previous Retinal Detachment	0.8%	0.0%	NS
Diabetic Retinopathy	3.1%	3.1%	NS
History of Prior Intraocular Surgery	0.0%	0.1%	NS

Cataracts Exhibit 4.15c: Distribution of Baseline Patients by Pre-Operative Comorbidity -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.15d: Distribution of Demo. Patients by Pre-Operative Comorbidity -- Site 3

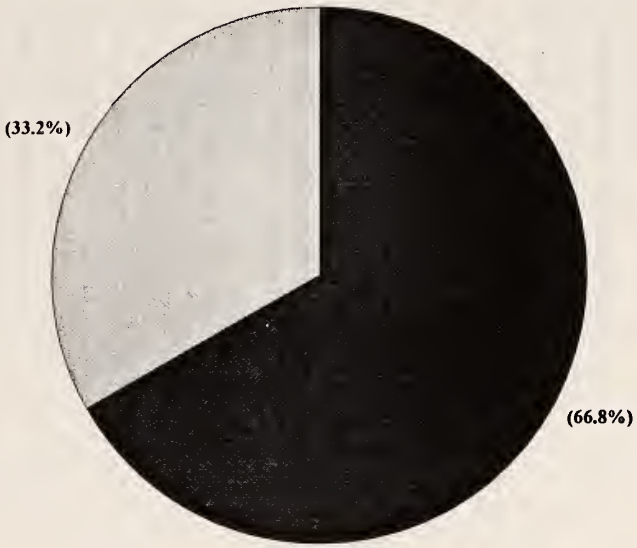


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Site 3 Patients by Pre-Operative Comorbidity -- Frequencies and Percentages

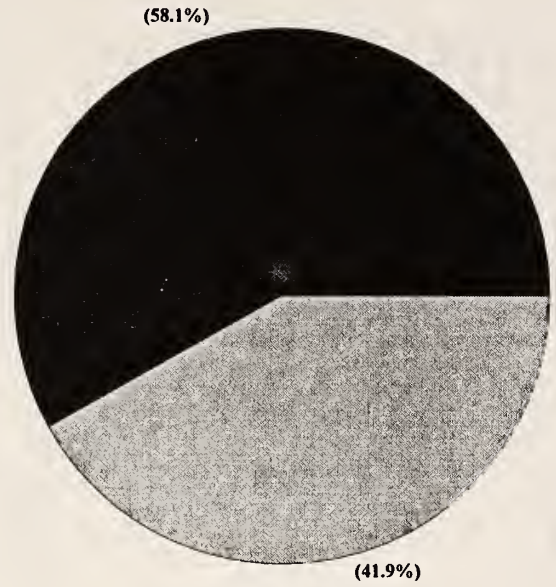
Pre-Operative Comorbidity	BASELINE PATIENTS -- SITE 3 Percentage of Baseline Patients With Indicated Pre-Operative Comorbidity	DEMONSTRATION PATIENTS -- SITE 3 Percentage of Demonstration Patients With Indicated Pre-Operative Comorbidity	T Test Result
No Ocular Disease Other than Cataract	69.7%	70.1%	NS
Amblyopia	1.1%	0.5%	NS
Age-Related Macular Degeneration	10.1%	13.9%	NS
Glaucoma	8.4%	7.8%	NS
Other Optic Nerve Disease	0.0%	0.4%	NS
Corneal Dystrophy/Opacification	3.4%	2.5%	NS
Chronic Uveitis or Keratitis	0.0%	0.5%	NS
Previous Retinal Detachment	1.1%	0.7%	NS
Diabetic Retinopathy	1.1%	2.6%	NS
History of Prior Intraocular Surgery	2.2%	0.8%	*

Cataracts Exhibit 4.15e: Distribution of Baseline Patients by Pre-Operative Comorbidity -- Site 4



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.15f: Distribution of Demo. Patients by Pre-Operative Comorbidity -- Site 4



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Site 4 Patients by Pre-Operative Comorbidity -- Frequencies and Percentages

Pre-Operative Comorbidity	BASELINE PATIENTS -- SITE 4: Percentage of Baseline Patients With Indicated Pre-Operative Comorbidity	DEMONSTRATION PATIENTS -- SITE 4: Percentage of Demonstration Patients With Indicated Pre-Operative Comorbidity	T Test Result
No Ocular Disease Other than Cataract	66.8%	58.1%	**
Amblyopia	1.0%	1.2%	NS
Age-Related Macular Degeneration	16.1%	20.6%	NS
Glaucoma	9.3%	8.4%	NS
Other Optic Nerve Disease	0.0%	0.9%	NS
Corneal Dystrophy/Opacification	2.0%	2.5%	NS
Chronic Uveitis or Keratitis	0.0%	0.4%	NS
Previous Retinal Detachment	0.5%	0.8%	NS
Diabetic Retinopathy	3.4%	2.9%	NS
History of Prior Intraocular Surgery	0.0%	0.1%	NS

Exhibit 4.16: Baseline versus Demonstration, Pre-Operative Tests

Baseline and Demonstration Patients by Pre-Operative Tests -- Frequencies and Percentages

Type of Pre-Operative Tests	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	T Test Result
A-Scan Ultrasonography	100.0%	100.0%	NS
B-Scan Ultrasonography	100.0%	100.0%	NS
Glare Testing	97.7%	98.1%	NS
Contrast Sensitivity Testing	0.8%	0.4%	NS
Color Vision Testing	0.0%	0.4%	NS
Dilated Fundus Examination	52.7%	71.0%	**
Keratometry	97.7%	99.0%	NS
Photography	2.3%	0.1%	NS
Assessment of Potential Acuity	0.0%	0.1%	NS
Specular Microscopy	0.0%	0.0%	NS
Formal Visual Field Testing	0.8%	0.1%	NS

Type of Pre-Operative Tests	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	T Test Result
A-Scan Ultrasonography	98.9%	98.0%	NS
B-Scan Ultrasonography	0.0%	2.0%	**
Glare Testing	29.8%	28.0%	NS
Contrast Sensitivity Testing	0.0%	0.3%	NS
Color Vision Testing	0.6%	0.1%	NS
Dilated Fundus Examination	80.9%	91.0%	**
Keratometry	97.2%	99.0%	*
Photography	0.0%	0.2%	NS
Assessment of Potential Acuity	2.2%	8.0%	**
Specular Microscopy	0.0%	0.4%	NS
Formal Visual Field Testing	1.1%	1.0%	NS

Type of Pre-Operative Tests	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients	T Test Result
A-Scan Ultrasonography	100.0%	100.0%	NS
B-Scan Ultrasonography	0.0%	0.5%	NS
Glare Testing	15.1%	42.0%	**
Contrast Sensitivity Testing	0.0%	2.0%	**
Color Vision Testing	0.0%	0.2%	NS
Dilated Fundus Examination	100.0%	99.0%	NS
Keratometry	100.0%	99.0%	NS
Photography	0.0%	0.4%	NS
Assessment of Potential Acuity	11.2%	43.0%	**
Specular Microscopy	0.0%	3.0%	**
Formal Visual Field Testing	0.5%	0.5%	NS

SOURCE (baseline v. demonstration): Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from late 1991 to 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Exhibit 4.17a: Baseline versus Demonstration Operative Techniques

Baseline and Demonstration Patients by Extraction Technique -- Frequencies and Percentages

	SITE 1	
Extraction Technique	Percentage of Baseline Patients	Percentage of Demo. Patients
ECCE	0.0%	0.0%
Phaco.	100.0%	99.9%
Converted	0.0%	0.1%
Other / Aborted	0.0%	0.0%
Missing Data	0.0%	0.0%

T Test on Percent Phacoemulsification Extration not significant for baseline and demonstration.

	SITE 3	
Extraction Technique	Percentage of Baseline Patients	Percentage of Demo. Patients
ECCE	42.1%	37.4%
Phaco.	57.3%	61.8%
Converted	0.0%	0.3%
Other / Aborted	0.6%	0.4%
Missing Data	0.0%	0.0%

T Test on Percent Phacoemulsification Extration not significant for baseline and demonstration.

	SITE 4	
Extraction Technique	Percentage of Baseline Patients	Percentage of Demo. Patients
ECCE	89.8%	43.5%
Phaco.	9.8%	56.2%
Converted	0.0%	0.2%
Other / Aborted	0.5%	0.1%
Missing Data	0.0%	0.0%

T Test on Percent Phacoemulsification Extration ** for baseline and demonstration

Baseline and Demonstration Patients by Capsulotomy Technique -- Frequencies and Percentages

	SITE 1	
Capsulotomy Technique	Percentage of Baseline Patients	Percentage of Demo. Patients
Can Opener	0.8%	0.8%
Scissors	0.8%	1.0%
Continuous Tear	98.4%	97.8%
Missing Data	0.0%	0.4%

T Test on Percent Continuous Tear not significant for baseline and demonstration.

	SITE 3	
Capsulotomy Technique	Percentage of Baseline Patients	Percentage of Demo. Patients
Can Opener	48.9%	39.0%
Scissors	0.6%	0.1%
Continuous Tear	50.6%	60.6%
Missing Data	0.0%	0.4%

T Test on Percent Continuous Tear *** for baseline and demonstration

	SITE 4	
Capsulotomy Technique	Percentage of Baseline Patients	Percentage of Demo. Patients
Can Opener	35.6%	2.3%
Scissors	0.0%	0.0%
Continuous Tear	63.9%	97.6%
Missing Data	0.5%	0.1%

T Test on Percent Continuous Tear *** for baseline and demonstration

SOURCE (baseline & demonstration) Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from late 1991 to 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients)

Exhibit 4.17b: Baseline versus Demonstration Operative Procedures

Baseline and Demonstration Patients by Type of IOL -- Frequencies and Percentages

	SITE 1	
Type of IOL	Percentage of Baseline Patients	Percentage of Demo. Patients
Standard PC IOL	100.0%	99.7%
Foldable PC IOL	0.0%	0.3%
Ant. Chamber IOL	0.0%	0.0%
Missing Data	0.0%	0.0%

T Test on Percent Standard PC IOL not significant.

	SITE 3	
Type of IOL	Percentage of Baseline Patients	Percentage of Demo. Patients
Standard PC IOL	92.7%	92.7%
Foldable PC IOL	0.6%	0.2%
Ant. Chamber IOL	0.6%	1.8%
Missing Data	6.2%	5.4%

T Test on Percent Standard PC IOL not significant.

	SITE 4	
Type of IOL	Percentage of Baseline Patients	Percentage of Demo. Patients
Standard PC IOL	90.7%	46.7%
Foldable PC IOL	8.8%	52.8%
Ant. Chamber IOL	0.0%	0.5%
Missing Data	0.5%	0.0%

T Test on Percent Standard PC IOL ***.

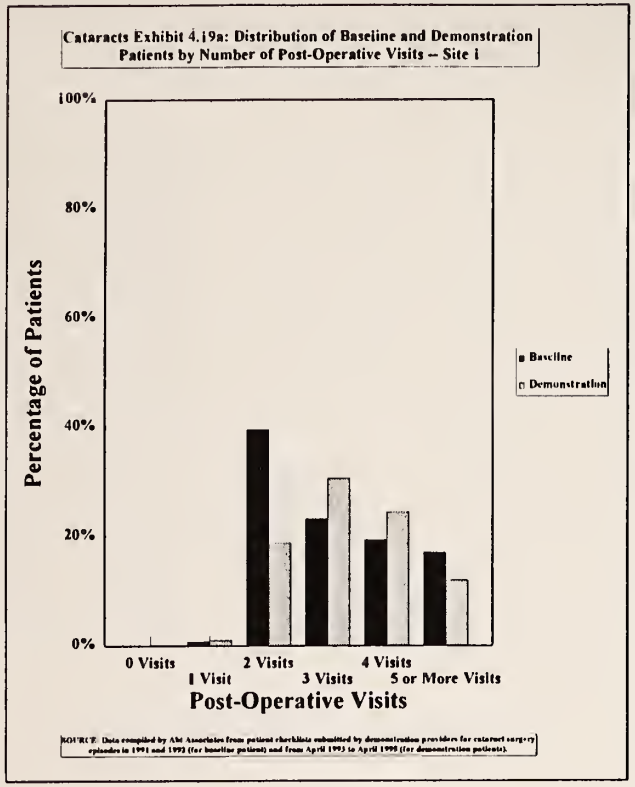
SOURCE (baseline & demonstration): Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from late 1991 to 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients)

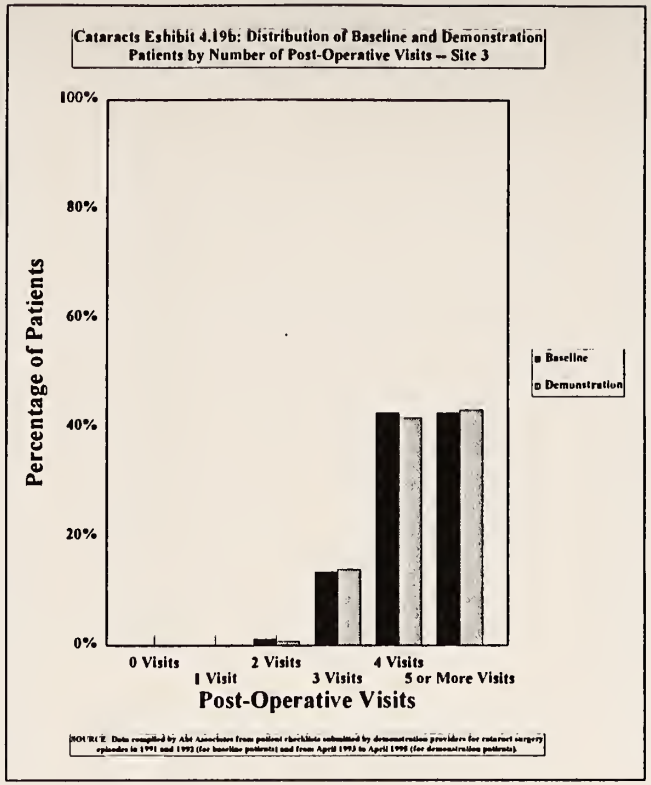
Exhibit 4.18: Cataract Patients by IOL Manufacturer and Model -- Percentages

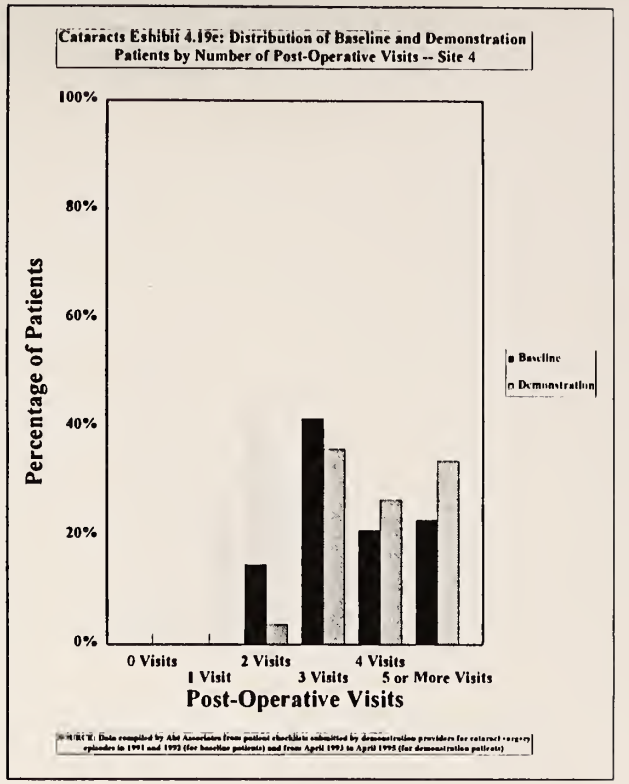
IOL Manufacturer	BASELINE – SITE 1 Model Number	BASELINE – SITE 1 Percentage of Baseline Patients	DEMONSTRATION – SITE 1 Model Number	DEMONSTRATION – SITE 1 Percentage of Demonstration Patients
IOLAB	Model #1	68.2%	Model #1	66.8%
			Model #3	18.2%
			All Other Models	0.5%
	Total	[illegible]	Total	[illegible]
ALCON/CILCO		2.3%		12.3%
COBURN		0.0%		0.0%
STAAR		0.0%		0.0%
IOPEX		0.0%		0.0%
STORZ		0.0%		0.1%
Eye Technology Inc. (Eye Tech)	Model #26	17.8%	Model #76	8.2%
	Model #38	11.7%	Model #5	2.1%
			All Other Models	2.1%
	Total	[illegible]	Total	12.4%
Chiron		0.0%		0.6%
Pharmacia		0.0%		0.0%
Allergan		0.0%		0.0%
AMO		0.0%		0.0%
SURGIDEV		0.0%		0.3%

IOL Manufacturer	BASELINE – SITE 3 Model Number	BASELINE – SITE 3 Percentage of Baseline Patients	DEMONSTRATION – SITE 3 Model Number	DEMONSTRATION – SITE 3 Percentage of Demonstration Patients
IOLAB		0.6%		0.1%
ALCON/CILCO	Model #4	25.3%	Model #4	31.2%
	Model #17	20.2%	Model #20	31.1%
	Model #22	3.9%	Model #17	26.3%
	All Other Models	2.4%	All Other Models	5.5%
	Total	[illegible]	Total	[illegible]
COBURN	Model #31	8.4%		0.0%
	Model #59	2.2%		
	Model #42	1.1%		
	Total	[illegible]		
STAAR		0.0%		0.3%
IOPEX		0.0%		0.0%
STORZ	Model #31	32.0%	Model #19	2.8%
	All Other Models	3.3%	All Other Models	2.5%
	Total	[illegible]	Total	[illegible]
Eye Technology Inc. (Eye Tech)		0.0%		0.0%
Chiron		0.0%		0.0%
Pharmacia		0.0%		0.0%
Allergan		0.0%		0.0%
AMO		0.0%		0.1%
SURGIDEV		0.0%		0.0%
Missing Data		0.0%		0.4%

IOL Manufacturer	BASELINE – SITE 4 Model Number	BASELINE – SITE 4 Percentage of Baseline Patients	DEMONSTRATION – SITE 4 Model Number	DEMONSTRATION – SITE 4 Percentage of Demonstration Patients
IOLAB	Model #2	54.1%	Model #42	17.4%
	Model #11	16.6%	Model #2	14.4%
	All Other Models	2.5%	All Other Models	2.7%
	Total	73.2%	Total	34.5%
ALCON/CILCO		6.8%	Model #24	6.9%
			All Other Models	1.6%
	Total	6.8%	Total	8.5%
COBURN		0.0%		0.1%
STAAR		3.4%	Model #8	48.0%
			Model #85	2.8%
			Model #30	1.8%
			All Other Models	0.6%
			Total	53.2%
IOPEX		0.0%		0.2%
STORZ		0.5%		2.7%
Eye Technology Inc. (Eye Tech)		0.0%		1.4%
Chiron	Model #46	7.3%		0.1%
Pharmacia	Model #48	7.3%		0.0%
Allergan		0.5%		0.1%
AMO		0.0%		0.0%
SURGIDEV		0.0%		0.0%
Missing Data		1.0%		0.1%


Cataracts Exhibit 4.19a: Distribution of Baseline and Demonstration Patients by Number of Post-Operative Visits -- Site 1
100%
80%
60%
40%
20%
0%
Percentage of Patients
0 Visits
1 Visit
2 Visits
3 Visits
4 Visits
5 or More Visits
Post-Operative Visits
Baseline
Demonstration
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1996 (for demonstration patients).


Cataracts Exhibit 4.19b: Distribution of Baseline and Demonstration Patients by Number of Post-Operative Visits -- Site 3
100%
80%
60%
40%
20%
0%
Percentage of Patients
0 Visits
1 Visit
2 Visits
3 Visits
4 Visits
5 or More Visits
Post-Operative Visits
Baseline
Demonstration
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1996 (for demonstration patients).

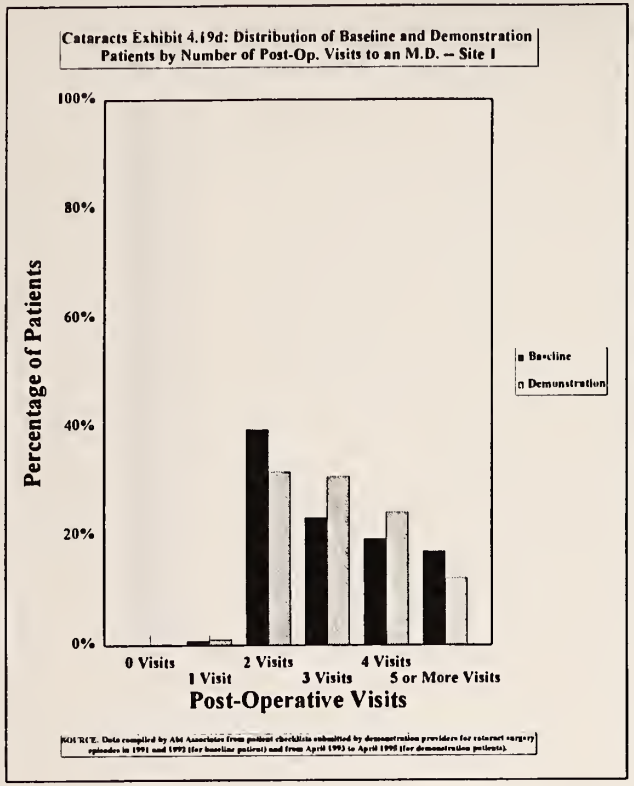

Cataracts Exhibit 4.19c: Distribution of Baseline and Demonstration Patients by Number of Post-Operative Visits -- Site 4
100%
80%
60%
40%
20%
0%
Percentage of Patients
0 Visits
1 Visit
2 Visits
3 Visits
4 Visits
5 or More Visits
Post-Operative Visits
Baseline
Demonstration
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1996 (for demonstration patients)

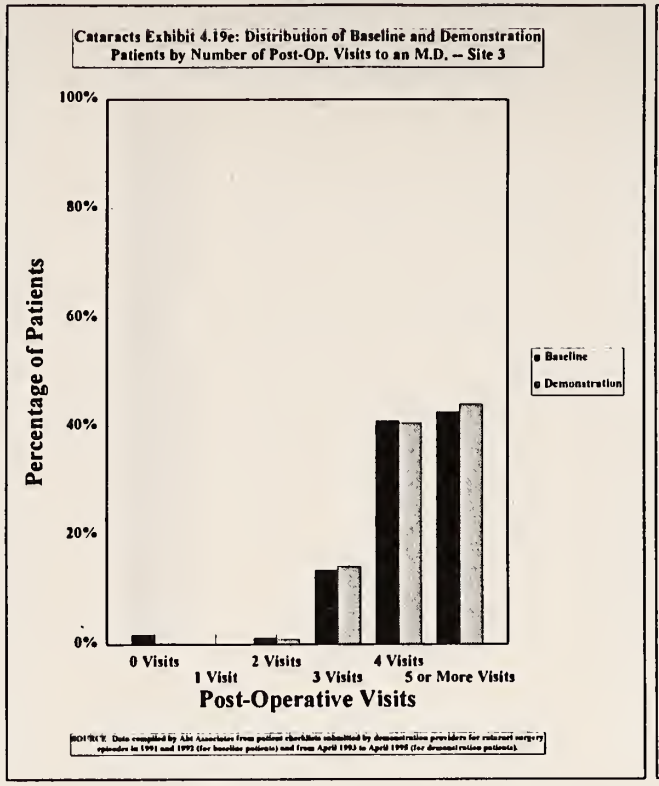
Cataracts Patients by Number of Post-Operative Visits -- Frequencies and Percentages

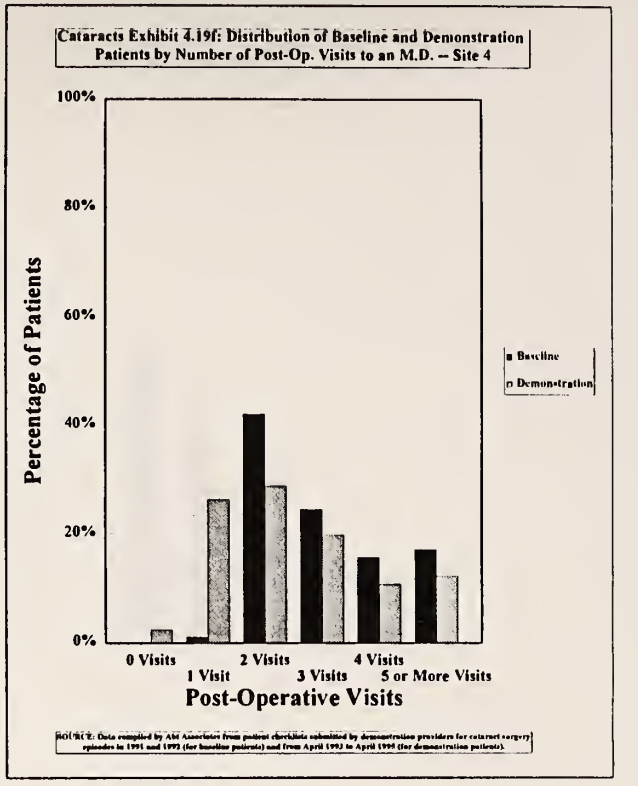
Number of Visits	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
0 Visits	0.0%	0.1%	0.0%	0.1%	0.0%	0.0%
1 Visit	0.8%	1.0%	0.0%	0.1%	0.0%	0.1%
2 Visits	39.5%	18.8%	1.1%	0.8%	14.6%	3.7%
3 Visits	23.3%	30.7%	13.5%	13.9%	41.5%	35.9%
4 Visits	19.4%	24.5%	42.7%	41.7%	21.0%	26.5%
5 or More Visits	17.1%	12.0%	42.7%	43.2%	22.9%	33.7%
Missing Data	0.0%	0.0%	0.0%	0.2%	0.0%	0.1%

Median and Mean Number of Post-Operative Visits

	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Post-Operative Visits	3 visits	3 visits		4 visits	4 visits		3 visits	4visits	
Mean Post-Operative Visits	3.30 visits	3.18 visits	t test NS	4.65 visits	4.70 visits	t test NS	3.74 visits	4.20 visits	t test **


Cataracts Exhibit 4.19d: Distribution of Baseline and Demonstration Patients by Number of Post-Op. Visits to an M.D. -- Site 1
100%
80%
60%
40%
20%
0%
Percentage of Patients
Baseline
Demonstration
0 Visits
1 Visit
2 Visits
3 Visits
4 Visits
5 or More Visits
Post-Operative Visits
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).


Cataracts Exhibit 4.19e: Distribution of Baseline and Demonstration Patients by Number of Post-Op. Visits to an M.D. -- Site 3
100%
80%
60%
40%
20%
0%
Percentage of Patients
Baseline
Demonstration
0 Visits
1 Visit
2 Visits
3 Visits
4 Visits
5 or More Visits
Post-Operative Visits
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).


Cataracts Exhibit 4.19f: Distribution of Baseline and Demonstration Patients by Number of Post-Op. Visits to an M.D. -- Site 4
100%
80%
60%
40%
20%
0%
Percentage of Patients
Baseline
Demonstration
0 Visits
1 Visit
2 Visits
3 Visits
4 Visits
5 or More Visits
Post-Operative Visits
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

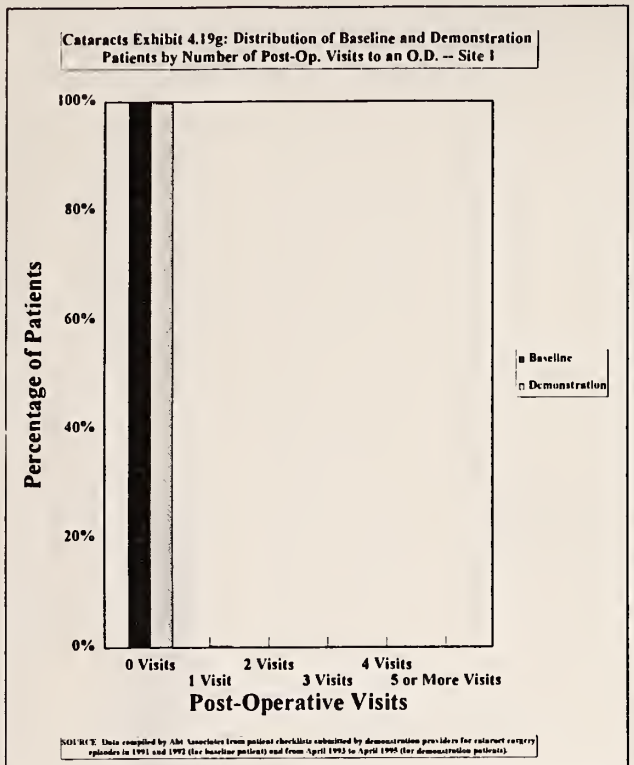
Cataracts Patients by Number of Post-Operative Visits to an M.D. -- Frequencies and Percentages

Number of Visits to an M.D	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
0 Visits	0.0%	0.1%	1.7%	0.2%	0.0%	2.4%
1 Visit	0.8%	1.0%	0.0%	0.1%	1.0%	26.3%
2 Visits	39.5%	31.7%	1.1%	0.9%	42.0%	28.7%
3 Visits	23.3%	30.8%	13.5%	14.2%	24.4%	19.7%
4 Visits	19.4%	24.2%	41.0%	40.6%	15.6%	10.7%
5 or More Visits	17.1%	12.2%	42.7%	44.1%	17.1%	12.2%
Missing Data	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Median and Mean Number of Post-Operative Visits to an M.D.

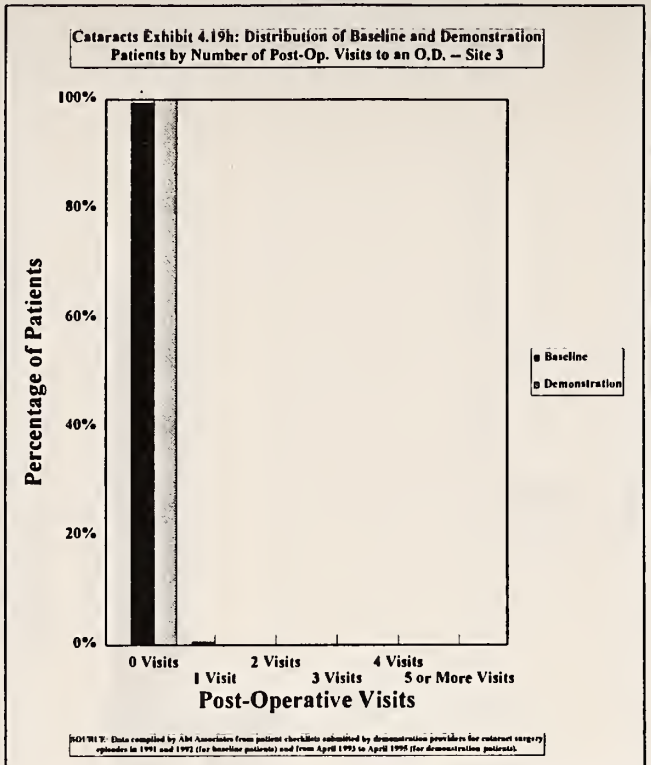
	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Post-Operative Visits	3 visits	3 visits		4 visits	4 visits		3 visits	2 visits	
Mean Post-Operative Visits	3.30 visits	3.17 visits	t test NS	4.58 visits	4.64 visits	t test NS	3.22 visits	2.55 visits	t test **

Cataracts Exhibit 4.19g: Distribution of Baseline and Demonstration Patients by Number of Post-Op. Visits to an O.D. -- Site 1



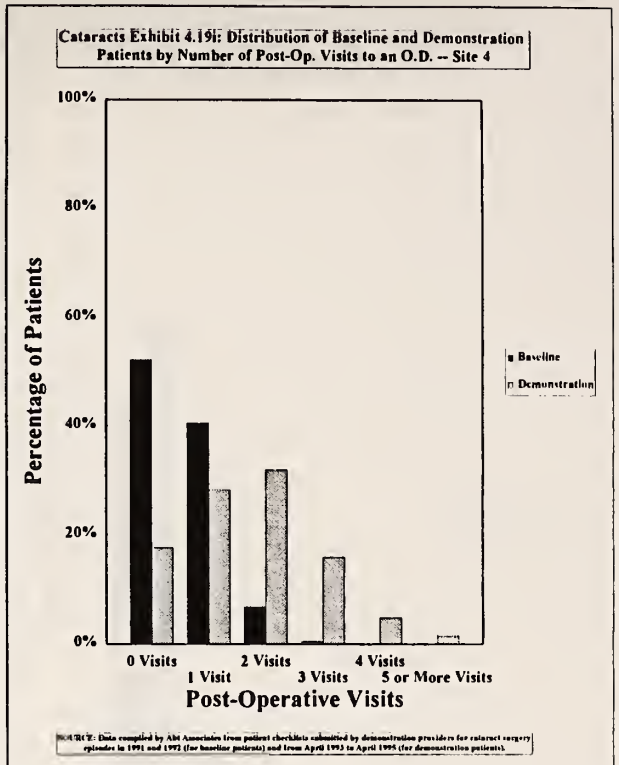
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19h: Distribution of Baseline and Demonstration Patients by Number of Post-Op. Visits to an O.D. -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19i: Distribution of Baseline and Demonstration Patients by Number of Post-Op. Visits to an O.D. -- Site 4



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

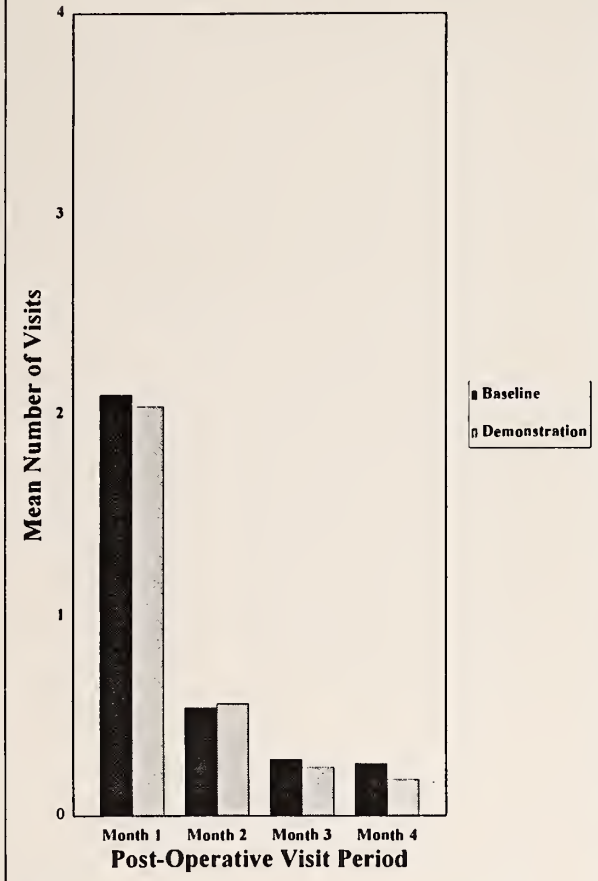
Cataracts Patients by Number of Post-Operative Visits to an O.D. -- Frequencies and Percentages

Number of Visits to an O.D.	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
0 Visits	100.0%	99.7%	99.4%	100.0%	52.2%	17.7%
1 Visit	0.0%	0.3%	0.6%	0.0%	40.5%	28.2%
2 Visits	0.0%	0.0%	0.0%	0.0%	6.8%	31.9%
3 Visits	0.0%	0.0%	0.0%	0.0%	0.5%	15.9%
4 Visits	0.0%	0.0%	0.0%	0.0%	0.0%	4.8%
5 or More Visits	0.0%	0.0%	0.0%	0.0%	0.0%	1.5%
Missing Data	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Median and Mean Number of Post-Operative Visits to an O.D.

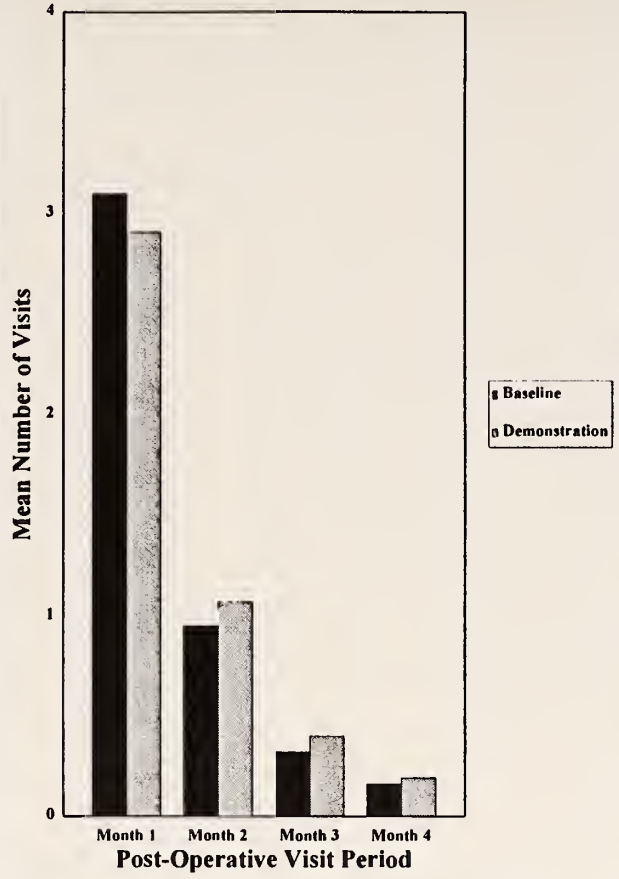
	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Post-Operative Visits	0 visits	0 visits		0 visits	0 visits		0 visits	2 visits	
Mean Post-Operative Visits	0 visits	.003 visits	t test NS	.02 visits	0 visits	t test **	0.56 visits	1.66 visits	t test **

Cataracts Exhibit 4.19j: Distribution of Baseline and Demonstration Patients by Post-Op. Visit by Month -- Site 1



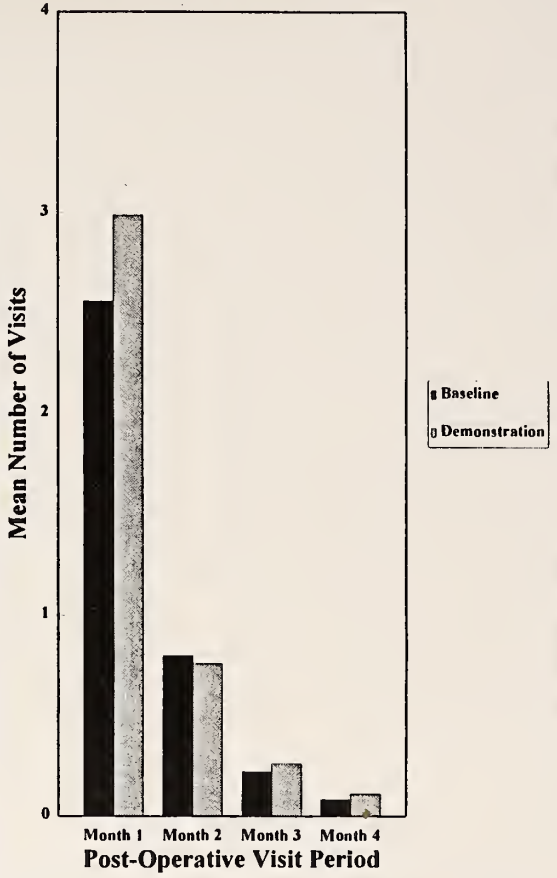
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19k: Distribution of Baseline and Demonstration Patients by Post-Op. Visit by Month -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19l: Distribution of Baseline and Demonstration Patients by Post-Op. Visit by Month -- Site 4

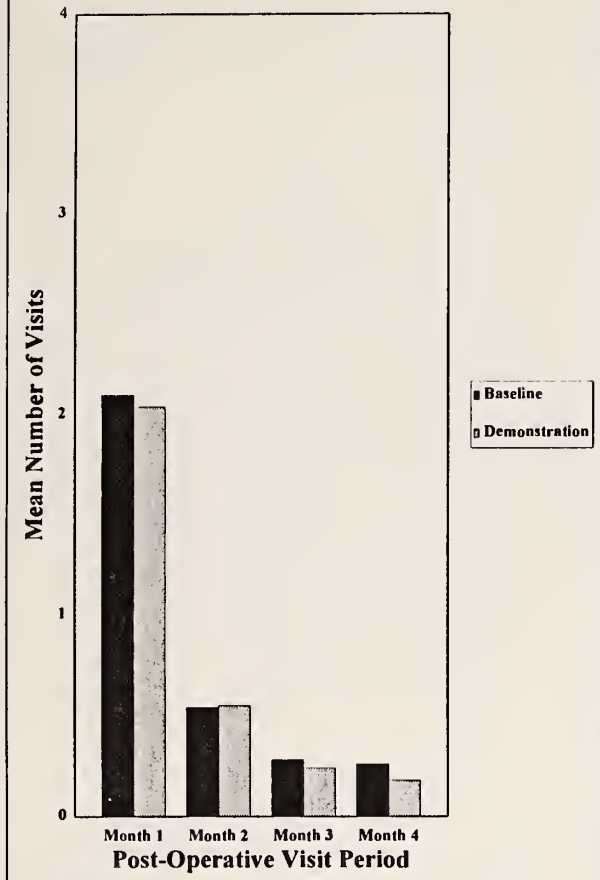


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Patients by Number of Post-Operative Visits by Month -- Frequencies and Percentages

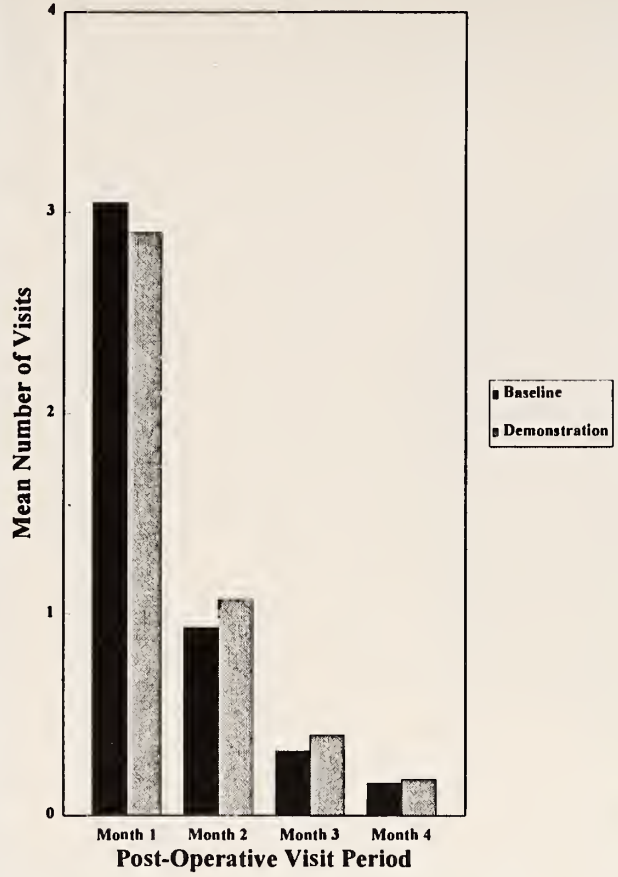
Post-Operative Visit Period	SITE 1 Mean Number of Baseline Visits	SITE 1 Mean Number of Demo. Visits	SITE 3 Mean Number of Baseline Visits	SITE 3 Mean Number of Demo. Visits	SITE 4 Mean Number of Baseline Visits	SITE 4 Mean Number of Demo. Visits
Month 1	2.10	2.04 NS	3.10	2.91 **	2.56	2.99 **
Month 2	0.54	0.56 NS	0.95	1.07 ***	0.80	0.76 NS
Month 3	0.28	0.24 NS	0.32	0.40 NS	0.22	0.26 NS
Month 4	0.26	0.18 **	0.16	0.19 NS	0.08	0.11 NS

Cataracts Exhibit 4.19m: Distribution of Baseline and Demonstration Patients by Post-Op. Visit to an M.D. by Month -- Site 1



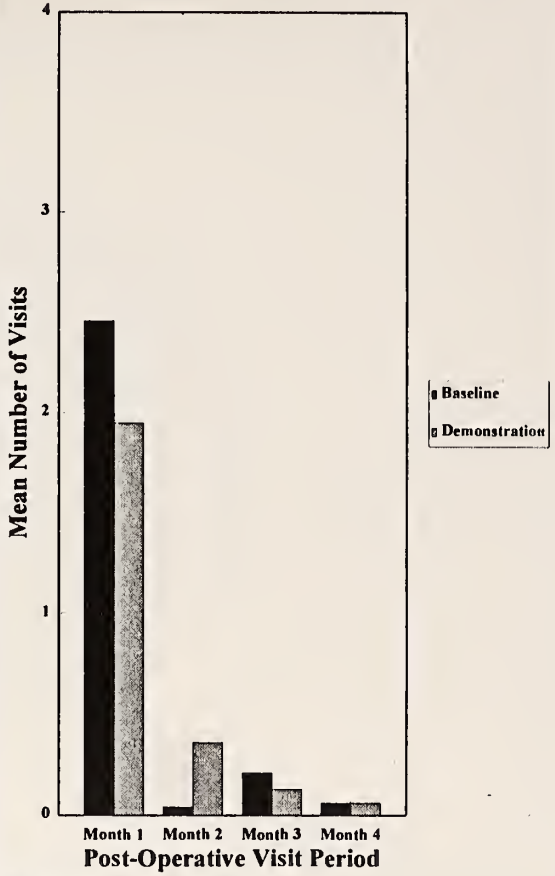
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19n: Distribution of Baseline and Demonstration Patients by Post-Op. Visit to an M.D. by Month -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19o: Distribution of Baseline and Demonstration Patients by Post-Op. Visit to an M.D. by Month -- Site 4

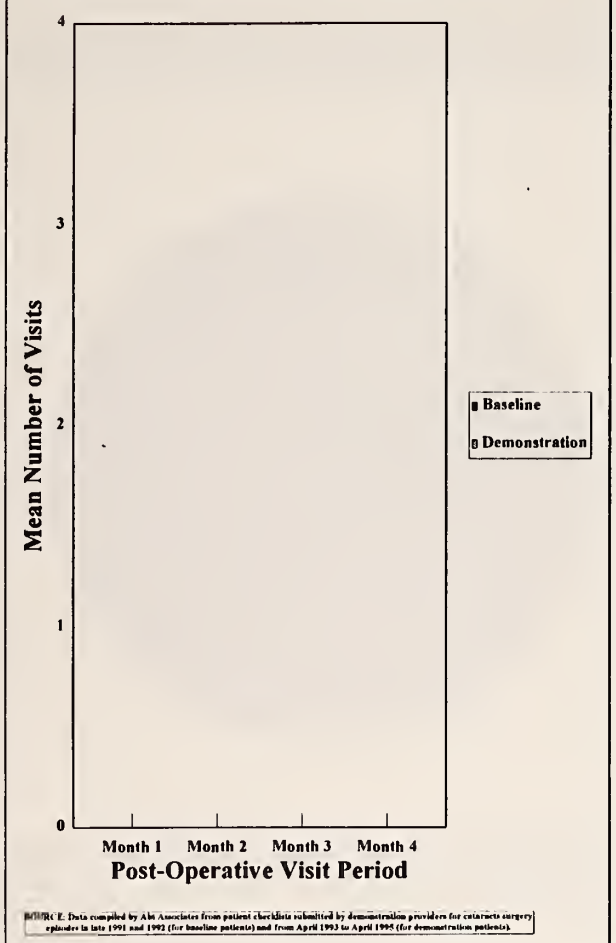


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Patients by Number of Post-Operative Visits to an M.D. by Month -- Frequencies and Percentages

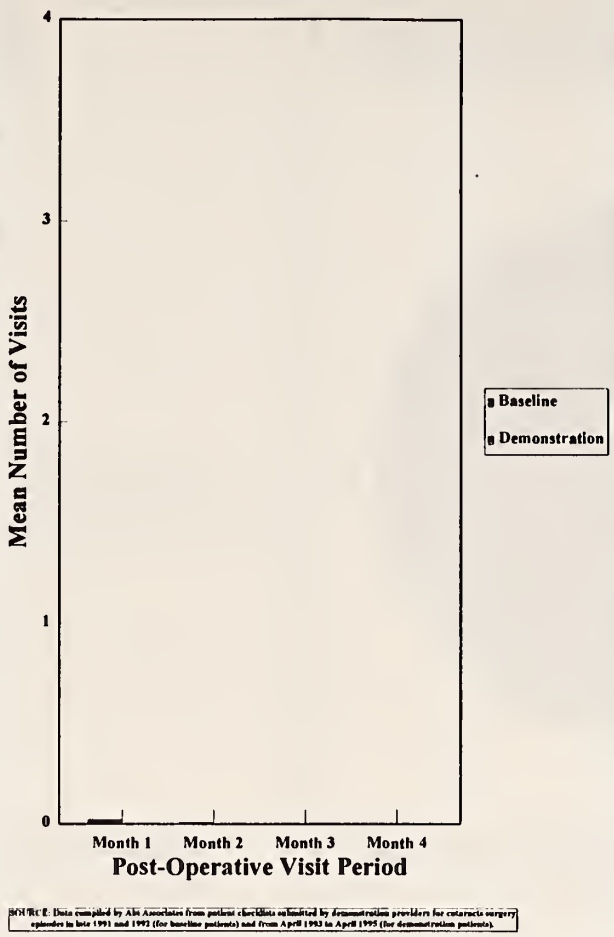
Post-Operative Visit Period	SITE 1		SITE 3		SITE 4	
	Mean Number of Baseline Visits	Mean Number of Demo. Visits	Mean Number of Baseline Visits	Mean Number of Demo. Visits	Mean Number of Baseline Visits	Mean Number of Demo. Visits
Month 1	2.10	2.04 NS	3.05	2.90 **	2.46	1.95 **
Month 2	0.54	0.55 NS	0.93	1.07 ***	0.04	0.36 NS
Month 3	0.28	0.24 NS	0.32	0.40 NS	0.21	0.13 **
Month 4	0.26	0.18 **	0.16	0.18 NS	0.06	0.06 NS

Cataracts Exhibit 4.19p: Distribution of Baseline and Demonstration Patients by Post-Op. Visit to an O.D. by Month -- Site 1



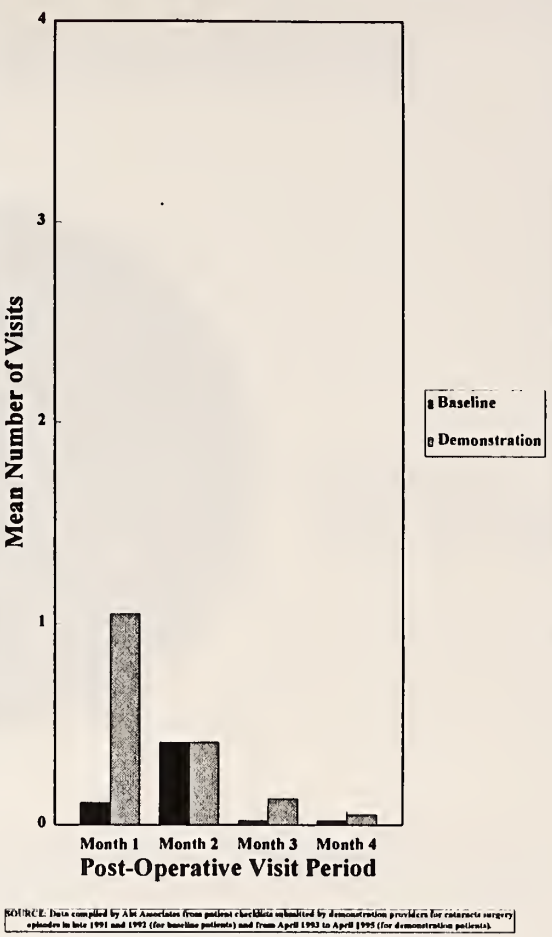
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19q: Distribution of Baseline and Demonstration Patients by Post-Op. Visit to an O.D. by Month -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.19r: Distribution of Baseline and Demonstration Patients by Post-Op. Visit to an O.D. by Month -- Site 4

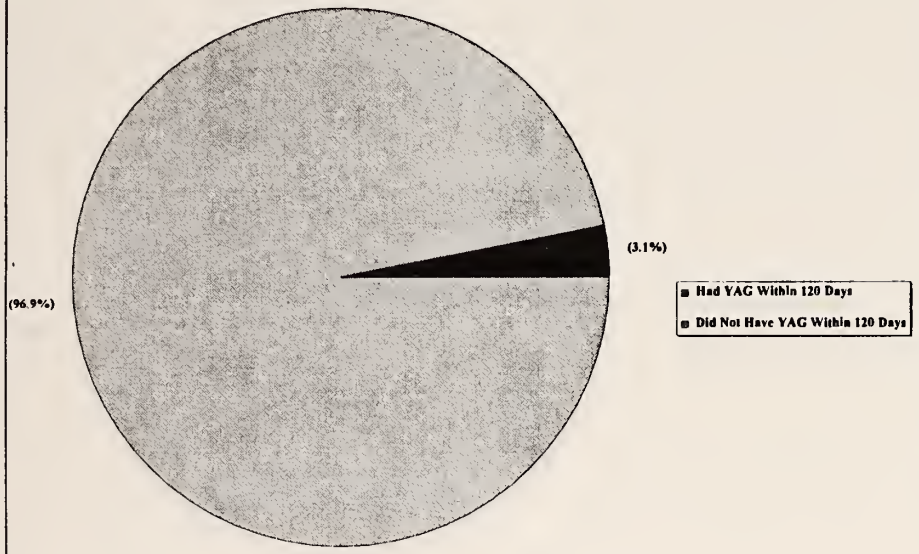


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataracts surgery episodes in late 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Patients by Number of Post-Operative Visits to an O.D. by Month -- Frequencies and Percentages

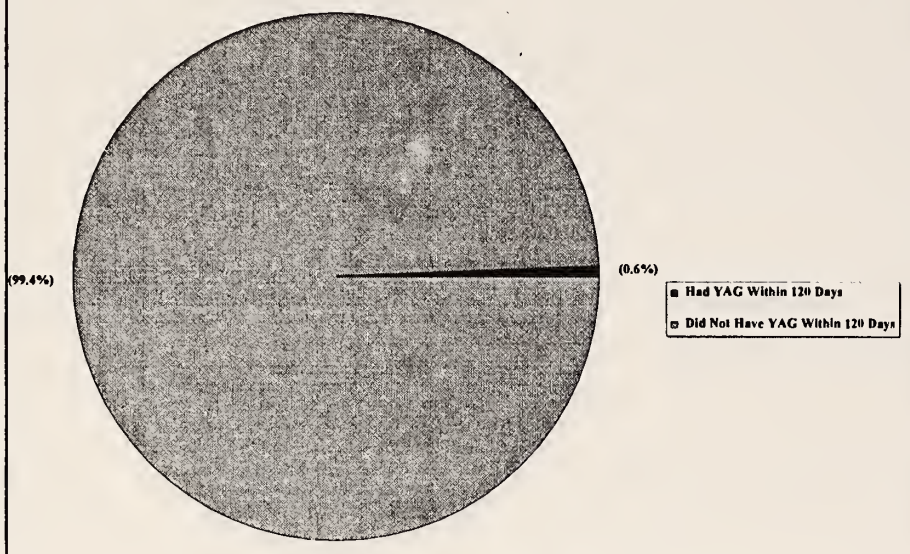
Post-Operative Visit Period	SITE 1 Mean Number of Baseline Visits	SITE 1 Mean Number of Demo. Visits		SITE 3 Mean Number of Baseline Visits	SITE 3 Mean Number of Demo. Visits		SITE 4 Mean Number of Baseline Visits	SITE 4 Mean Number of Demo. Visits	
Month 1	0.00	0.001	NS	0.02	0.00	**	0.11	1.05	**
Month 2	0.00	0.001	NS	0.006	0.00	***	0.41	0.41	NS
Month 3	0.00	0.000	NS	0.00	0.00	NS	0.02	0.13	***
Month 4	0.00	0.000	**	0.00	0.00	NS	0.02	0.05	*

Cataracts Exhibit 4.20a: Distribution of Baseline Patients Who Had a YAG Capsulotomy Within 120 Days of Surgery -- Site 1



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.20b: Distribution of Demonstration Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Site 1

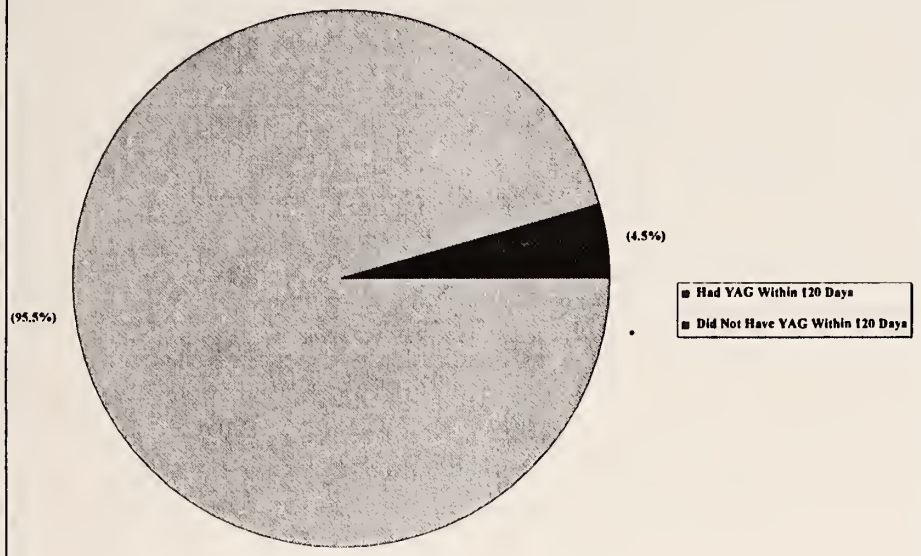


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Site 1 Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Frequencies and Percentages

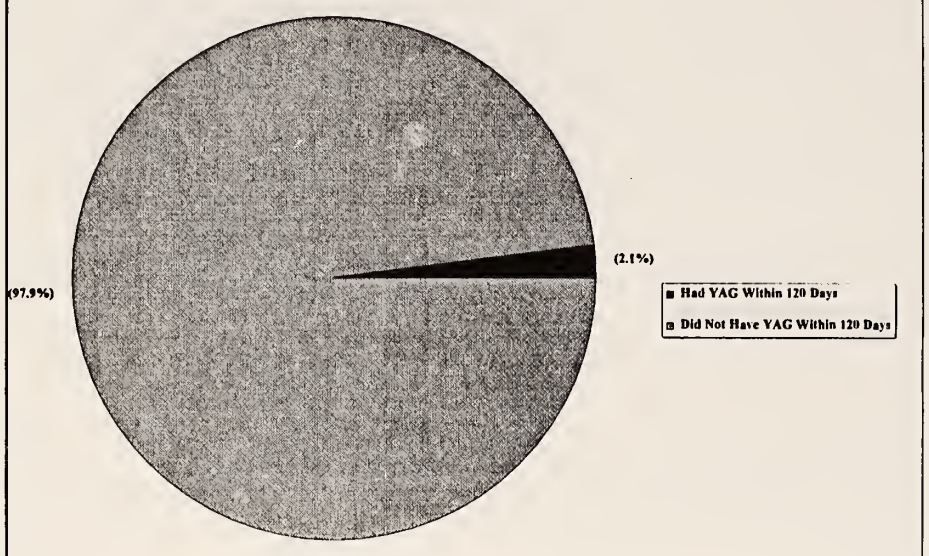
YAG Capsulotomy Within 120 Days After Surgery	BASELINE -- SITE 1 Percentage of Baseline Patients	DEMONSTRATION -- SITE 1 Percentage of Demonstration Patients	
Yes	3.1%	0.6%	t test pct. "YES" ***
No	96.9%	99.4%	

Cataracts Exhibit 4.20c: Distribution of Baseline Patients Who Had a YAG Capsulotomy Within 120 Days of Surgery -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.20d: Distribution of Demonstration Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Site 3

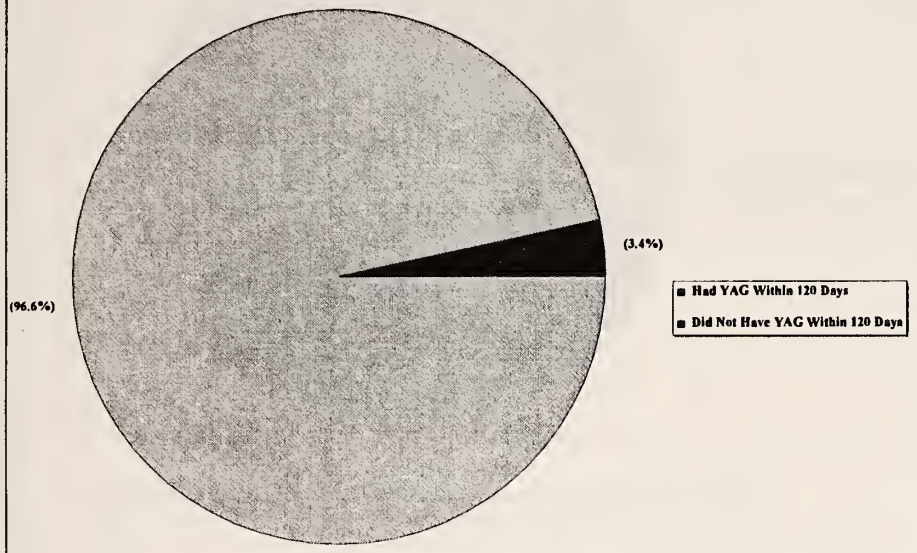


SOURCE: Data compiled by Abt Associates from patient checklist data submitted by demonstration providers f cataract surgery episodes form April 1993 to April 1995.

Site 3 Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Frequencies and Percentages

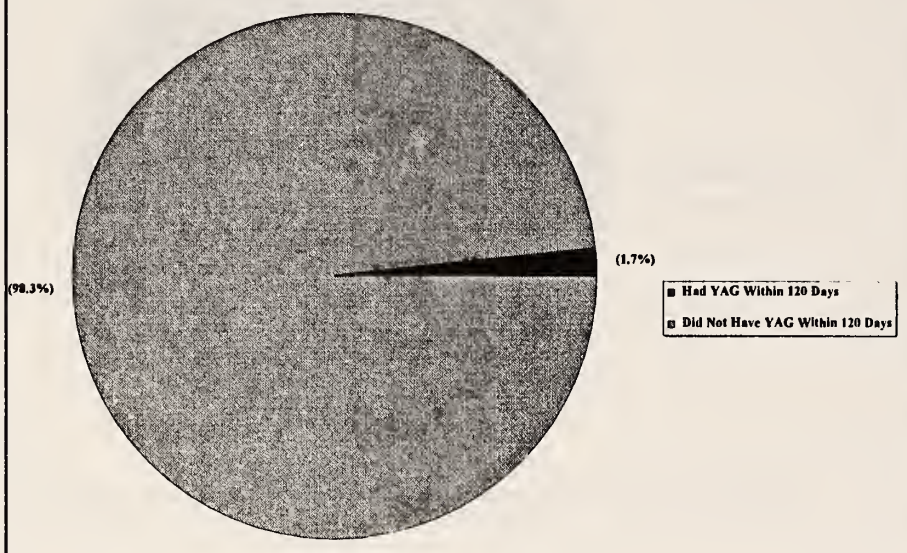
YAG Capsulotomy Within 120 Days After Surgery	BASELINE – SITE 3 Percentage of Baseline Patients	DEMONSTRATION – SITE 3 Percentage of Demonstration Patients	
Yes	4.5%	2.1%	t test pct. "YES" **
No	95.5%	97.9%	

Cataracts Exhibit 4.20e: Distribution of Baseline Patients Who Had a YAG Capsulotomy Within 120 Days of Surgery -- Site 4



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

Cataracts Exhibit 4.20f: Distribution of Demonstration Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Site 4

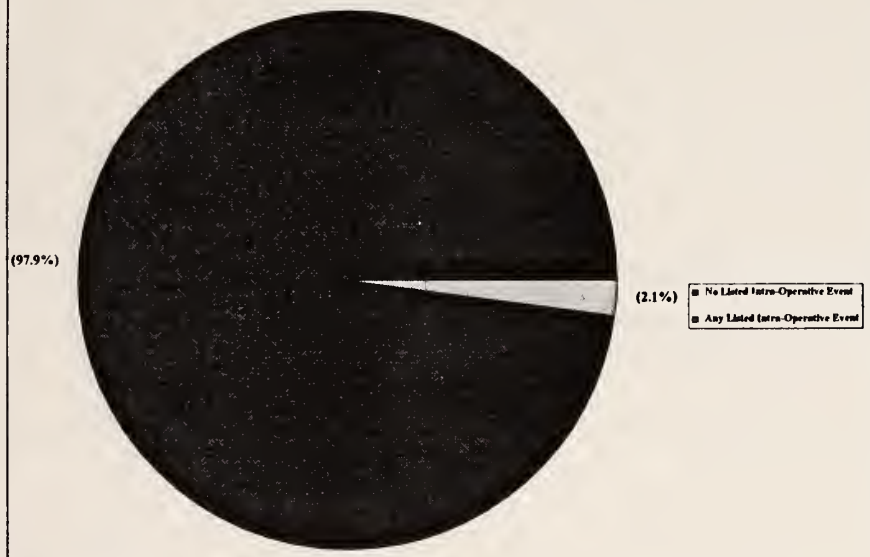


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Site 4 Patients Who Had a YAG Capsulotomy Within 120 Days After Surgery -- Frequencies and Percentages

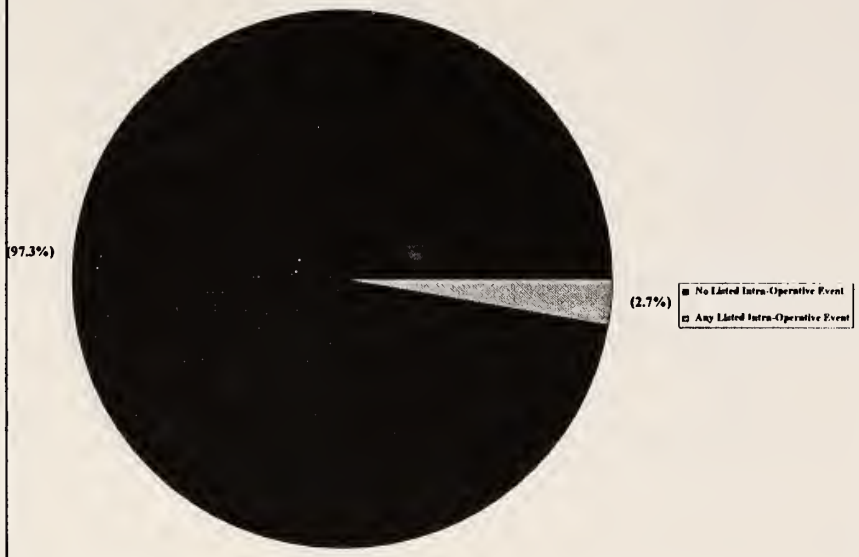
YAG Capsulotomy Within 120 Days After Surgery	BASELINE -- SITE 4 Percentage of Baseline Patients	DEMONOSTRATION -- SITE 4 Percentage of Demonstration Patients	
Yes	3.4%	1.7%	t test pct. "YES" *
No	96.6%	98.3%	

Cataracts Exhibit 4.21a: Distribution of Baseline Patients by Intra-Operative Event -- All Sites



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery from late 1991 to 1992.

Cataracts Exhibit 4.21b: Distribution of Demonstration Patients by Intra-Operative Event -- All Sites

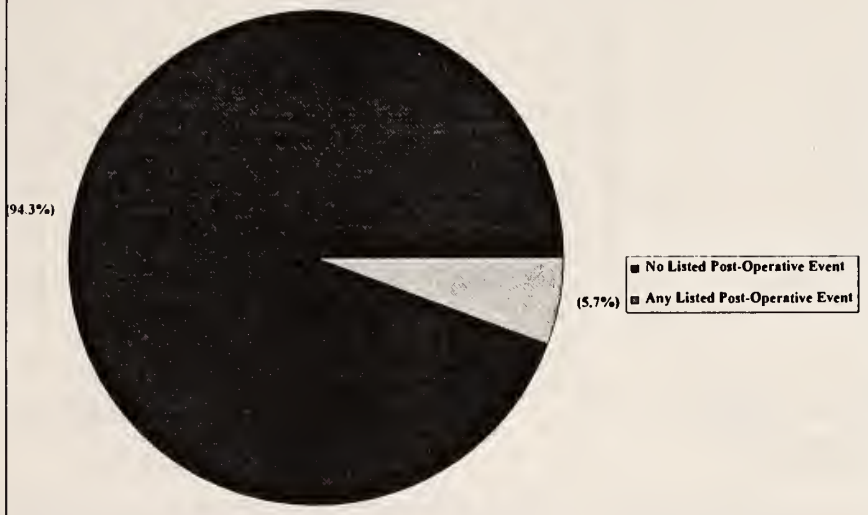


SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Cataract Patients by Intra-Operative Event -- Percentages

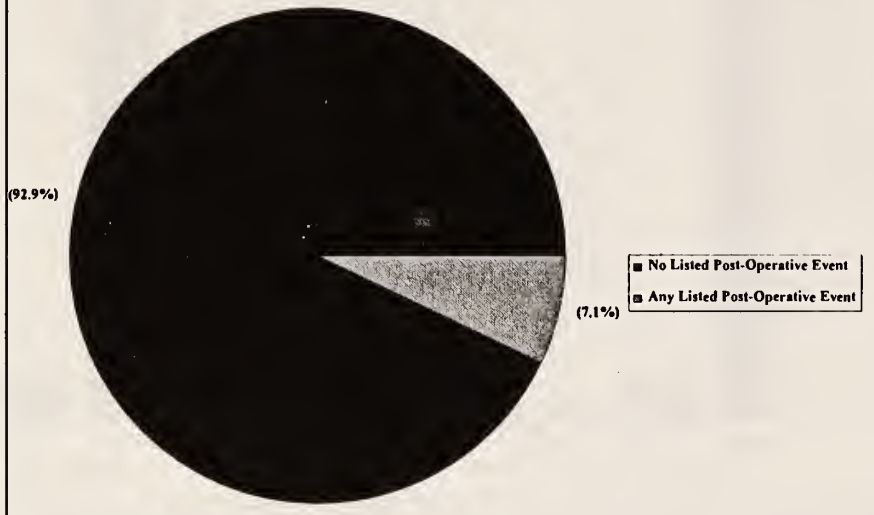
Intra-Operative Event	BASELINE - ALL SITES: Percentage of Baseline Patients Experiencing Indicated Intra-Operative Event	DEMONSTRATION - ALL SITES: Percentage of Demonstration Patients Experiencing Indicated Intra-Operative Event	T Test Result
No Listed Intra-Operative Event	97.6%	96.3%	NS
Posterior Capsular/ Zonal Rupture	1.2%	2.1%	NS
Vitreous Loss	1.2%	1.3%	NS
Posterior Loss of Nuclear Fragment	0.0%	0.2%	NS
Choroidal Hemorrhage	0.0%	0.0%	NS
Retrobulbar Hemorrhage	0.0%	0.0%	NS
Globe Perforation	0.0%	0.0%	NS
Anterior Hemorrhage	0.0%	0.1%	NS
Any Listed Intra-Operative Event	2.1%	2.7%	NS

Cataracts Exhibit 4.22a: Distribution of Baseline Patients by Post-Operative Event -- All Sites



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes in late 1991 and 1992.

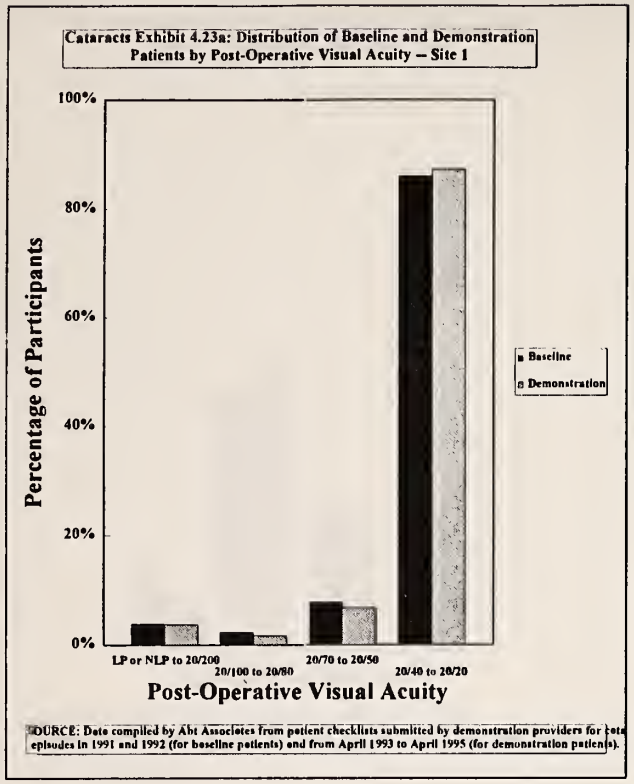
Cataracts Exhibit 4.22b: Distribution of Demonstration Patients by Post-Operative Event -- All Sites

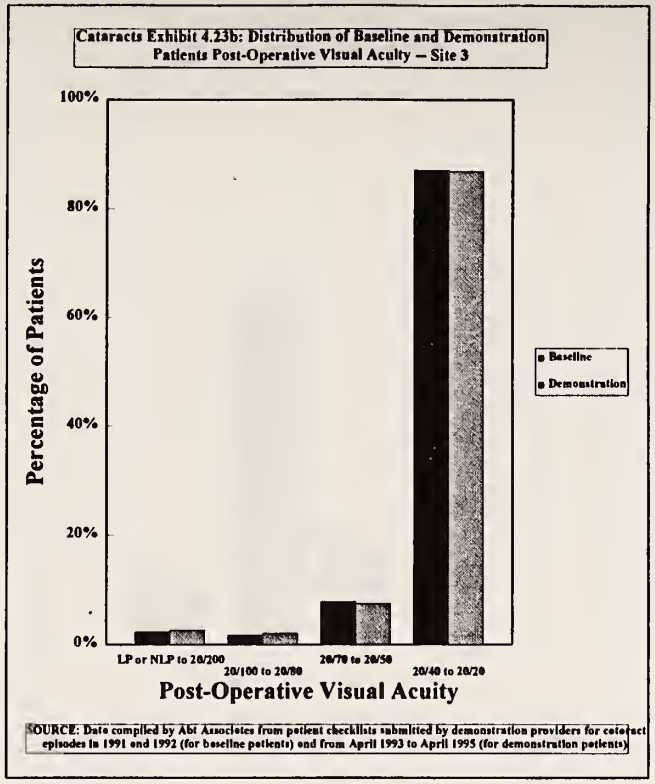


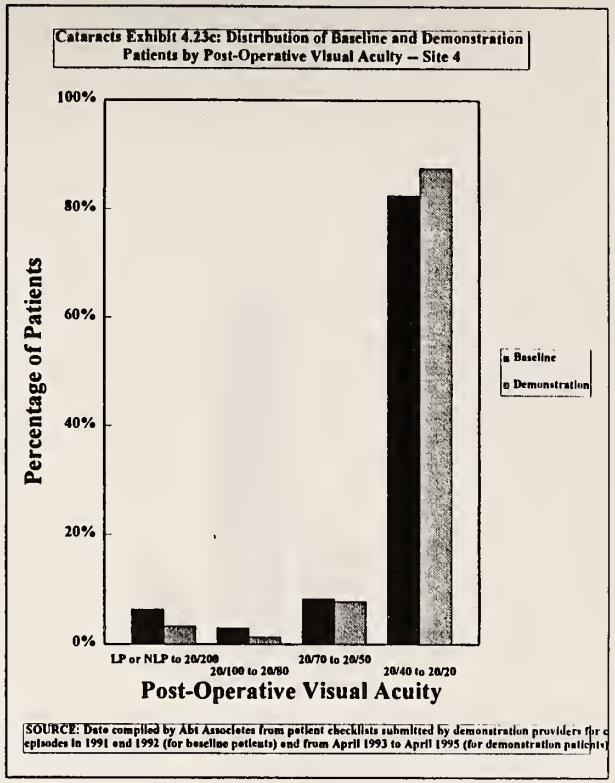
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract surgery episodes from April 1993 to April 1995.

Cataract Patients by Post-Operative Event -- Percentages

Post-Operative Event	BASELINE - ALL SITES: Percentage of Baseline Patients Experiencing Indicated Post-Operative Event (N = 512)	DEMONSTRATION - ALL SITES: Percentage of Demonstration Patients Experiencing Indicated Post-Operative Event (N = 3,585)	T Test Result
No Listed Post-Operative Event	94.1%	92.5%	NS
Endophthalmitis	0.0%	0.1%	NS
IOL Dislocation	0.4%	0.7%	NS
Wound Leak/ Rupture	0.0%	0.4%	NS
Retinal Tear/ Detachment	0.0%	0.1%	NS
Elevated IOP	0.8%	0.5%	NS
Persistent Iritis	0.8%	0.2%	***
Cystoid Macular Edema	1.0%	1.4%	NS
Corneal Edema	2.9%	4.1%	NS
Any Listed Post-Operative Event	5.7%	7.1%	NS


Cataracts Exhibit 4.23a: Distribution of Baseline and Demonstration Patients by Post-Operative Visual Acuity -- Site 1
100%
80%
60%
40%
20%
0%
Percentage of Participants
LP or NLP to 20/200
20/100 to 20/80
20/70 to 20/50
20/40 to 20/20
Post-Operative Visual Acuity
Baseline
Demonstration
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cata
episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).


Cataracts Exhibit 4.23b: Distribution of Baseline and Demonstration Patients Post-Operative Visual Acuity -- Site 3
100%
80%
60%
40%
20%
0%
Percentage of Patients
LP or NLP to 20/200
20/100 to 20/80
20/70 to 20/50
20/40 to 20/20
Post-Operative Visual Acuity
Baseline
Demonstration
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract
episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).


Cataracts Exhibit 4.23c: Distribution of Baseline and Demonstration Patients by Post-Operative Visual Acuity -- Site 4
100%
80%
60%
40%
20%
0%
Percentage of Patients
LP or NLP to 20/200
20/100 to 20/80
20/70 to 20/50
20/40 to 20/20
Post-Operative Visual Acuity
Baseline
Demonstration
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for c
episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Patients by Post-Operative Visual Acuity -- Frequencies and Percentages

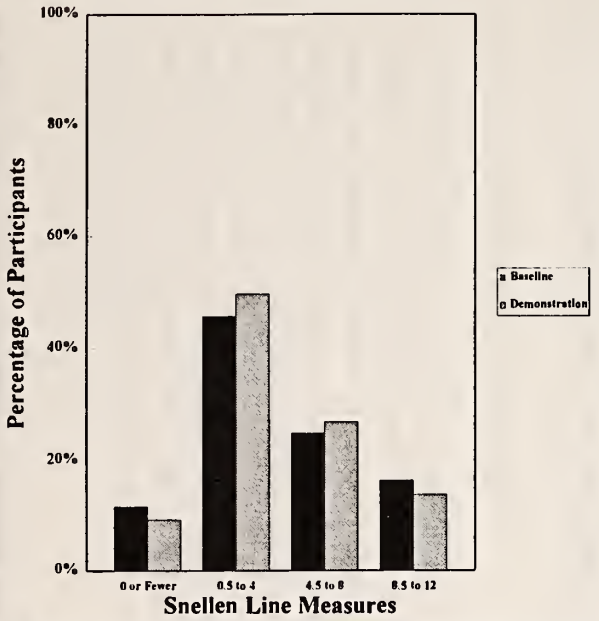
Post-Operative Acuity Distribution	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
LP or NLP to 20/200	3.9%	3.8%	2.2%	2.6%	6.3%	3.2%
20/100 to 20/80	2.3%	1.7%	1.7%	2.1%	2.9%	1.2%
20/70 to 20/50	7.8%	6.7%	7.9%	7.5%	8.3%	7.8%
20/40 to 20/20	86.0%	87.3%	87.1%	87.0%	82.4%	87.5%
Missing Data	0.0%	0.5%	1.1%	0.9%	0.0%	0.2%

Median and Mean Post-Operative Acuity

	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Post-Operative Acuity	20/25	20/25		20/25	20/25		20/25	20/25	
Mean Post-Operative Acuity	.756	.767	t test NS	.75	.75	t test NS	.71	75	t test **

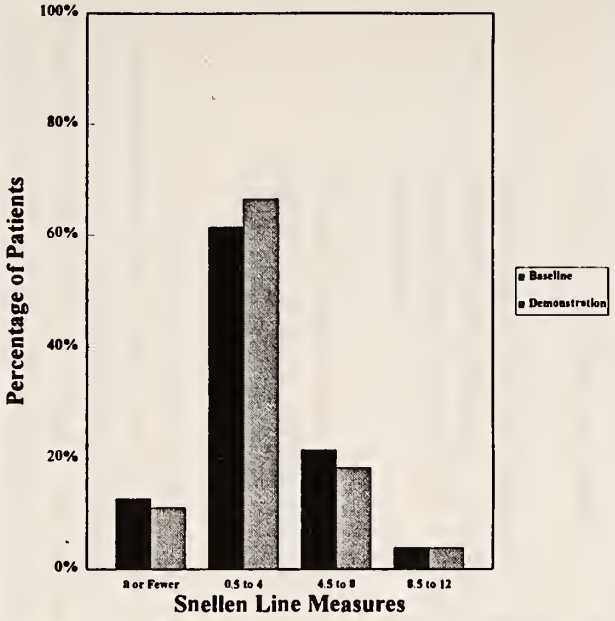
NOTE: Baseline and demonstration mean post-operative visual acuities are between 20/30 (.67) and 20/25 (.80) for all sites.

Cataracts Exhibit 4.24a: Distribution of Baseline and Demonstration Patients by Change in Snellen Lines -- Site 1



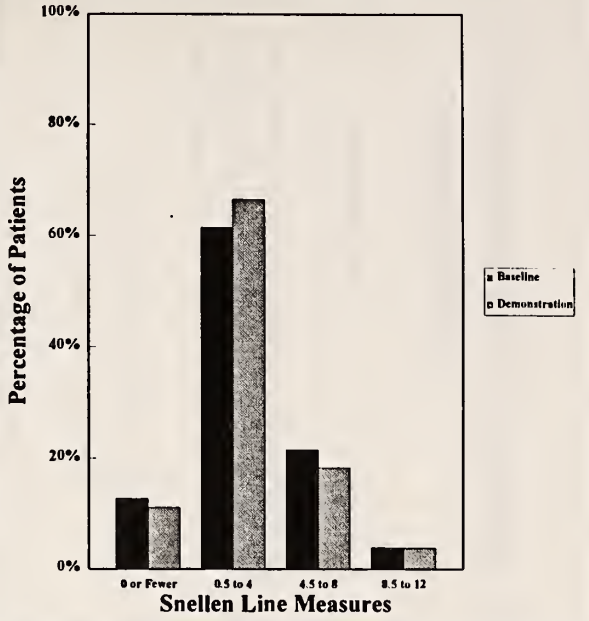
SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cata episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.24b: Distribution of Baseline and Demonstration Patients Change in Snellen Lines -- Site 3



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for cataract episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Exhibit 4.24c: Distribution of Baseline and Demonstration Patients by Change in Snellen Lines -- Site 4



SOURCE: Data compiled by Abt Associates from patient checklists submitted by demonstration providers for c episodes in 1991 and 1992 (for baseline patients) and from April 1993 to April 1995 (for demonstration patients).

Cataracts Patients by Change in Snellen Lines -- Frequencies and Percentages

Snellen Line Measure	SITE 1 Percentage of Baseline Patients	SITE 1 Percentage of Demo. Patients	SITE 3 Percentage of Baseline Patients	SITE 3 Percentage of Demo. Patients	SITE 4 Percentage of Baseline Patients	SITE 4 Percentage of Demo. Patients
0 or Fewer	11.6%	9.2%	6.2%	5.6%	12.7%	11.1%
0.5 to 4	45.7%	49.7%	41.0%	48.3%	61.5%	66.5%
4.5 to 8	24.8%	26.8%	42.1%	36.1%	21.5%	18.3%
8.5 to 12	16.3%	13.7%	9.6%	8.4%	3.9%	3.8%
12.5 or more	1.6%	0.5%	0.0%	0.4%	0.5%	0.2%
Missing Data	0.0%	0.1%	1.1%	0.0%	0.0%	0.2%

Median and Mean Snellen Line Change

	SITE 1 Baseline	SITE 1 Demonstration		SITE 3 Baseline	SITE 3 Demonstration		SITE 4 Baseline	SITE 4 Demonstration	
Median Snellen Line Change	4	4		5	4		3	3	
Mean Snellen Line Change	4.49	4.30	t test NS	4.73	4.48	t test NS	3.28	3.14	t test NS

NOTE: Baseline and demonstration mean post-operative visual acuities are between 20/30 (.67) and 20/25 (.80) for all sites.

5.0 Summary and Conclusion: Lessons Learned from the Demonstration

5.1 Introduction

The preceding sections have discussed the major impacts of the demonstration that can be measured or observed from the limited data available to the evaluation. These sections have discussed the following major impacts:

- intensive and organized opposition to the demonstration by most major elements of the ophthalmologic community;
- very low response rates to HCFA's solicitation efforts in the demonstration cities;
- initiatives to reduce per-episode costs by most demonstration providers;
- inability of providers to increase their volumes of cataract surgery through the demonstration, although it may have allowed them to maintain volume at pre-demonstration levels in the face of declines among most of their non-demonstration competitors;
- evidence that levels of service were maintained during the demonstration, some evidence that services were provided more efficiently, no evidence that the demonstration had any impact on patient outcomes.

This section will begin with a discussion of what we consider to be the major lessons learned from the demonstration in light of these findings. This is followed by a concluding section which evaluates the overall success of the demonstration in relation to its original objectives. We begin with an examination of the issue of provider opposition; specifically: Why did the project engender such concerted and strong opposition from the ophthalmologic community?

5.2 Lessons Learned from the Demonstration

Provider Opposition to the Demonstration

The Medicare Cataract Surgery Alternate Payment Demonstration provides a case history for healthcare planners and researchers in the difficulties of mounting a demonstration in the face of strong and organized opposition from one of the major impacted providers. In this regard, it is important to note that ophthalmologists, although key players, were not the only provider groups affected by the project. Facilities, represented by hospitals (insofar as their outpatient departments were used for cataract surgery) and ASCs were also impacted. On the professional side, other physicians, mainly anesthesiologists, were also included among the provider groups whose services were included in the bundle. Given that a variety of providers were potentially impacted by the project, why were ophthalmologists and later anesthesiologists the only provider groups to take up arms against the project?

We postulate the answer lies in the Medicare reimbursement experience of ophthalmologists in the years immediately preceding the demonstration. Specifically, we are referring to the reductions which occurred between the late 1980s and the early 1990s in Medicare's allowed charge levels for cataract surgeons. By the late 1980s, Medicare had classified cataract surgery as an "overpriced procedure," and introduced a series of regulatory changes which effectively reduced its allowed charge levels for the procedure by 25 percent between 1986 and 1991. Moreover, even with these past reductions, the future looked just as bleak to most cataract surgeons. In 1992, HCFA was to begin the transition to its resource-based relative value scale (RBRVS) which would set rates prospectively each year for the full range of physicians services, including surgeon's fees. It was well known at the time that one of the major impacts of RBRVS was a correction to what was seen as a longstanding imbalance in Medicare's previous physician reimbursement system. Put simply, this imbalance was seen as an overcompensation of surgeons for procedural, technology-driven services such as surgery, and an underpayment of physicians, particularly those in primary care, for cognitive and evaluative type services, such as comprehensive assessments and physical exams. Consequently, cataract surgeons viewed themselves as victims, not only of the immediate past, but very likely for the foreseeable future, in the Medicare program.

Moreover, because cataracts primarily afflict the elderly, Medicare represented a significant share of almost all cataract surgeons' business. Although most ophthalmologists were not high-volume surgeons—one study[27] showed that the vast majority of Medicare cataract extractions were performed by surgeons with fewer than 200 cases annually—the majority of ophthalmologists performed a fair number of these procedures. This last factor probably accounts for the depth of opposition to the demonstration in the ophthalmologic community.

Given the persistent payment reductions in their recent experience with Medicare and the absence of brighter prospects in the future, it is not difficult to understand the degree of opposition the demonstration encountered from this segment of the provider community. It was probably viewed as another in a long series of moves by the Government to reduce their compensation for cataracts services.

Is there a lesson to be learned from the cataract demonstration's experience that could be applied to future projects? Probably the only lesson is that provider groups who have been subjected to persistent and significant payment reductions, other options being equal, should be avoided, when possible, when developing plans for future cost containment demonstrations. The other lesson is the difficulty that organized provider opposition can add to the implementation and successful operations of a demonstration.

Volume/Outcome Relationship

We have noted elsewhere in this report that HCFA was implementing a similar bundled payment demonstration for CABG surgery during the same period as the cataracts project. The CABG demonstration encompassed most of the same design elements as cataracts, including minimal incentives for providers to propose large bundle discounts due to the non-exclusive nature of provider participation in the project, and the absence of strong financial incentives for beneficiaries to select

27 Javitt, Jonathan C., MD, MPH, "Who Does Cataract Surgery in the United States?", *ARCH Ophthalmol*, Vol. III; 1329, October 1993.

demonstration providers. Some have naturally asked why the CABG project received no significant opposition from interested provider groups and the cataracts project did, given the similar design elements of both projects? While the explanation given above accounts for the majority of opposition to the cataracts demonstration, there was another important difference between the two projects. That factor was the absence of any scientific evidence of a positive relationship between higher volumes and improved outcomes for cataract surgery as opposed to ample evidence of such a relationship for CABG procedures.

The absence of such a relationship for cataract procedures prevented HCFA from using one of the strongest justifications it had for developing the CABG initiative; namely, to test methods to channel beneficiaries to high-volume, high-quality facilities and practitioners to reduce the risk and improve patient outcomes for these procedures in Medicare. The volume/outcome factor provided a strong clinical and qualitative rationale for the CABG demonstration that was not available in the cataracts project. Thus, when confronted by charges from the ophthalmologic community that the project represented merely another in a long attempt by the Government to negatively impact their income levels, there was no clinical/qualitative justification, as there was for the CABG project.

This leads us to a discussion of another apparent difference between the two projects relevant to savings potential.

Diminished Savings Opportunities

There is no question the CABG demonstration had a much higher savings potential than the cataracts project. Costs of CABG cases were in the $30,000 to $50,000 range and were considered quite profitable by most hospitals. In contrast, cataracts cases were in the $2,000 to $4,000 cost range and payment levels had been declining steadily.

Aside from these cost differentials, a question could also be raised about whether the cataracts demonstration presented opportunities for significant program savings given the recent history of allowable charge reductions for most major components of the bundle. As noted above and in Section 1.0, in the years leading up to the demonstration, Medicare had achieved significant price reductions in three key components of the episode: 1) the facility fee as it applies to mainly hospital outpatient departments but to a lesser extent also to ASCs; 2) allowable charge levels for the IOL; and 3) the surgeon's fee. Given these reductions, one could question whether the net impact of the reductions was to diminish or even eliminate opportunities for the demonstration to achieve significant savings.

There is no question the cumulative impacts of these fee reductions diminished the opportunities for achieving large savings from the bundle project. In this regard, these impacts probably occurred at two levels. On the basic level of economics or cost accounting, these prior fee reductions had narrowed the gap between a provider's true costs to provide the services and Medicare's allowance for such services. On the more psychological level, these reductions, along with other related design features of the project, probably convinced most providers they had nothing to gain financially by taking part in the study.

But while savings opportunities were reduced by these past reduction efforts, they were by no means totally eliminated. As evidence of this fact, we need go no further than to quote one ophthalmologist

participating in the project. In an interview with the trade industry publication, *In Sight Focus*,[28] the physician observed the following about the demonstration:

> "One of the arguments against the project is that there are only a few dollars in savings. That is true. No one wanted to put in a bid that was $500 to $600 lower than what we are now receiving. But if the government really puts it out to bid, I guarantee we will see prices tumble. Then we are going to see the inefficient physician no longer doing cataract surgery. And heaven knows there are a lot of inefficient surgeons out there."

Thus, anecdotal evidence seems to suggest that there were still opportunities for sizeable cost reductions among providers of cataract surgery services. Implicit in this quote is a related observation that the incentives contained in the project's design failed to elicit a vigorous price competition that would result in such dramatic price reductions.

The lesson learned from the savings opportunity question is similar to that proffered earlier. Other factors being equal, it is probably prudent to avoid projects designed to produce program savings for provider groups who have been subject to significant recent payment reductions in the conventional payment system.

Improved Efforts to Anticipate and Avoid Provider Billing Problems with Supplemental Insurers

We noted earlier that all demonstration providers experienced significant problems in billing and collecting deductible and coinsurance amounts from supplemental (Medigap) insurers. It is apparent that more efforts should have been devoted to identifying and investigating this problem when the demonstration design was being developed. Two possible approaches seem now to have promise. The first would have involved an attempt, at least, to design a unique EOMB for the bundle payment which matched the line item fields on the regular EOMB as much as possible. Given that the cataracts bundle was limited to Part B services, it doesn't seem beyond the realm of possibility that an EOMB could have been designed that listed each particular service included in the bundle (by real or proxy HCPCS procedure codes) and arrayed the submitted, allowed, and paid charges (all based on the terms of the demonstration) for processing by Medigap insurers. A second approach would have been to include resources for education and outreach efforts to supplemental insurers as an important task in project implementation. This approach would essentially take the extensive education and outreach efforts that HCFA took after the demonstration had begun and move them to the pre-operations phase to reduce the impacts of this problem on participating providers. Together, both approaches would probably have significantly reduced but not eliminated the problems experienced by providers in collecting payments for the patient liability portion of Part B allowable charges.

Cost Efficiency Initiatives of Providers

Although available evidence suggests the demonstration produced only modest savings for the Medicare program, and according to demonstration providers, did not lead to increased surgical volumes within the organizations, anecdotal evidence indicates that it did prompt most providers to more carefully examine their cost structure for the surgical episode and initiate actions to reduce these

---

28 "Insight Focus: A Policy Issue Analysis from Insight Reports," Volume 10, No. 3, February 11, 1994.

expenditures. These actions included efforts to standardize the procurement of some or all of the materials used in the procedure, including the IOL at two sites. One provider, Site 4, cited the benefits of the demonstration as a learning experience. The demonstration prompted this provider to carefully examine all its cost components for the episode and to develop per episode costs for each surgeon in the practice. The provider felt this and other actions would place the practice in a better position to compete for managed care business in both the public and private sectors.

Encouraging providers to become more efficient was one of the major goals of the demonstration and it appears to have had such an impact at most of the project's providers. It is rather easy for these positive impacts to be ignored in evaluating the larger, program-specific impacts of the project. Yet, they are important findings which, if applied to a much larger universe of providers, might have significant long-term impacts on the Medicare program as well.

5.3 Summary and Conclusion

The final issue to be addressed in this report is to provide a general assessment of the overall success of the demonstration in meeting HCFA's original objectives. Despite the provider hostility and lower savings opportunity discussed above, the demonstration was remarkably successful in meeting most of its original objectives. A brief summary of the demonstration's performance relative to each of these objectives follows.

Provider Flexibility in Managing Bundle Services. On this objective the project could be judged a reasonable success. Although the demonstration imposed demanding quality standards in its provider selection criteria, once providers satisfied these criteria and became participating providers, they had complete freedom to decide the type and amount of services to provide to demonstration patients, and who within the provider organization should provide those services.

Incentives for Cost Effectiveness. There is ample anecdotal evidence that the demonstration was successful in meeting this objective within most provider organizations. These cost reduction efforts included changes made by surgeons in the techniques and time required to perform the surgery and actions to standardize the IOLs and other supplies and materials used in the episode to reduce costs. In addition, the demonstration prompted one provider to perform a more comprehensive evaluation of all cost inputs to the episode.

Reduced Government Involvement In Pricing Bundle Services. This is not an easy objective to evaluate, mainly due to the design and selection criteria of the demonstration. On one hand, one could say that through the provider application and negotiation process the Government was intimately involved in all aspects of how applicants proposed to price and pay for all components of the bundle. On the other hand, once demonstration operations began, Government activities related to pricing were greatly reduced and limited to simple verification and payment of the global fee negotiated with each participation provider organization. Thus, on this measure also, the demonstration can be judged a reasonable success.

Provide Insight into Appropriateness Indicators, Quality Assurance and Utilization Review Mechanisms. On this multi-faceted objective the demonstration would have to be considered a partial success. As noted earlier, circumstances prevented us from performing the beneficiary survey which

was to be an essential tool in developing the appropriateness indicators for cataract surgery. On this factor at least, the project did not meet its objective. On the quality control and utilization review components of this objective, the demonstration could be termed successful, as indicated by the unchanged outcomes of demonstration patients reported in Section 4.0.

Provide Information Regarding Factors Influencing Providers' Decisions to Participate and Beneficiaries' Decisions to Select Demonstration Providers. Here again, the project has to be judged a partial success. On the provider level, the project produced valuable new insights on the strengths and weaknesses of particular incentives in encouraging providers to participate in a voluntary and non-exclusive demonstration. However, in general, the project did not shed much light on what factors influenced decisions by beneficiaries to select participating providers. Of course, one reason this objective was not fulfilled was because the beneficiary survey could not be performed. Failure to meet this objective was not due to any intrinsic weakness in the overall design of the project. Nevertheless, in general, we would have to say the entire objective was only partially achieved.

Taking into account the demonstration's performance across all of these objectives, we think the overall conclusion is that the demonstration was a success. The valuable experience and lessons learned from this project have and will be used by HCFA to revise the design features of bundled payment programs and to apply these new approaches to future studies of this payment mechanism.

Appendix A

Demonstration Patient Checklist

PATIENT CHECKLIST

Medicare Cataract Surgery Alternate Payment Demonstration

Batch 1-3

Patient Name: _____ Phone: ( ) _____

Address: _____

Date of Birth: ___/___/___ (mm dd yy) Medicare No: _____ Operative Date: ___/___/___ (mm dd yy)

Surgeon Name: _____ Date Surgery Decided: ___/___/___ (mm dd yy)

PREOPERATIVE DATA

1. Operative Eye *(check one)*: Right (OD) ☐ 1 Left (OS) ☐ 2

2a. Significant Preoperative Ocular Pathology *(check all that apply in column 2a)*

2b. Is There a Guarded Prognosis for Achieving 20/25 or Better Postoperatively?

Yes ☐ 1 *(If Yes, check all conditions affecting outcome in column 2b)* No ☐ 2

2a	2b		2a	2b	
☐ 1	☐ 2	No ocular disease other than cataract	☐ 1	☐ 2	Chronic uveitis or keratitis
☐ 3	☐ 4	Amblyopia	☐ 3	☐ 4	Previous retinal detachment
☐ 1	☐ 2	Age-related macular degeneration	☐ 1	☐ 2	Diabetic retinopathy
☐ 3	☐ 4	Glaucoma	☐ 3	☐ 4	History of prior intraocular surgery
☐ 1	☐ 2	Other optic nerve disease	☐ 1	☐ 2	Other retinal vascular disease
☐ 3	☐ 4	Corneal dystrophy/opacification	☐ 3	☐ 4	Other *(specify)* _____

3. Tests Performed Preoperatively *(check all that apply)*:

- ☐ 1 A-Scan ultrasonography
- ☐ 2 B-Scan ultrasonography
- ☐ 3 Glare testing
- ☐ 4 Contrast sensitivity testing
- ☐ 5 Color vision testing
- ☐ 6 Dilated fundus examination
- ☐ 1 Keratometry
- ☐ 2 Photography *(anterior segment or fundus)*
- ☐ 3 Assessment of potential acuity
- ☐ 4 Specular microscopy
- ☐ 5 Formal visual field testing
- ☐ 6 None of the above
- ☐ 7 Other *(specify)* _____

4. Best Corrected Preoperative Distance Acuity:

(circle one if appropriate)

Right (OD): 20/___ ___ ___ CF HM LP NLP

Left (OS): 20/___ ___ ___ CF HM LP NLP

5. Preoperative Refraction for Operative Eye:

+ / - ___ ___ ___ ___ (circle, sphere) + / - ___ ___ ___ ___ (cyl) x ___ ___ ___ (axis)

6. Lens Condition *(check all that apply)*:

	Right (OD)	Left (OS)
Clear lens	☐ 1	☐ 2
Nuclear cataract	☐ 3	☐ 4
Cortical cataract	☐ 1	☐ 2
Posterior subcapsular cataract	☐ 3	☐ 4
Aphakia	☐ 1	☐ 2
Pseudophakia	☐ 3	☐ 4
Other *(specify)* _____	☐ 1	☐ 2

7. Intraocular Pressure:

Right (OD) ___ ___ mm

Left (OS) ___ ___ mm

8. Axial Length *(for operative eye)*:

___ ___ . ___ ___ mm

Medicare No: _____

Operative Eye: Right (OD)_____ Left (OS)_____

OPERATIVE DATA

1. **Type of Surgery Performed** *(check one)*:

- ☐ 1 Extracapsular with manual nuclear expression
- ☐ 2 Extracapsular with iris plane/anterior chamber phacoemulsification
- ☐ 3 Posterior chamber phacoemulsification
- ☐ 4 Converted *(phaco converted to manual extracap)*
- ☐ 5 Intracapsular
- ☐ 6 Other *(specify)* _____
- ☐ 7 Surgery aborted

2. **IOL Implanted** *(check one)*:

- ☐ 1 Posterior chamber standard
- ☐ 2 Posterior chamber foldable
- ☐ 3 Anterior chamber
- ☐ 4 Suture-fixated IOL
- ☐ 5 Multifocal IOL
- ☐ 6 No IOL implanted

Manufacturer: _____

Model Number: _____

3. **Largest Incision Length:** ___ ___ ___ mm

4. **Type of Capsulotomy** *(check one)*:

- ☐ 1 Can opener with cystotome/needle
- ☐ 2 Scissors
- ☐ 3 Continuous tear

5. **Significant Intraoperative Events:**

(check all that apply)

- ☐ 1 Posterior capsular/zonular rupture
- ☐ 2 Vitreous loss/anterior vitrectomy
- ☐ 3 Posterior loss of nuclear fragment
- ☐ 4 Choroidal hemorrhage
- ☐ 5 Retrobulbar hemorrhage
- ☐ 6 Globe perforation during anesthesia
- ☐ 7 Anterior chamber hemorrhage
- ☐ 8 Other *(specify)* _____

Medicare No: _____

Operative Eye: Right (OD)_____ Left (OS)_____

POSTOPERATIVE DATA

1. Postoperative Events Occurring Between Surgery and Last Post-op Visit

(Date: ___/___/___) For Operative Eye:
mm dd yy

PRESENT ANYTIME BETWEEN SURGERY AND LAST POST-OP VISIT
(check all that apply)

- ☐ 1 Endophthalmitis
- ☐ 2 IOL dislocation *(pupil optic misalignment)*
- ☐ 3 Wound leak/rupture
- ☐ 4 Retinal tear/detachment
- ☐ 5 Other *(specify)*_____

PRESENT AT LAST POST-OP VISIT
(check all that apply)

- ☐ 1 Elevated IOP *(not requiring treatment preoperatively)*
- ☐ 2 Persistent iritis
- ☐ 3 Cystoid macular edema
- ☐ 4 Corneal edema: peripheral ☐ central ☐
- ☐ 5 Other *(specify)*_____

2. Best Corrected Distance Vision at Last Post-op Visit:

(circle one if appropriate)

Right (OD): 20/___ ___ ___ CF HM LP NLP

Left (OS): 20/___ ___ ___ CF HM LP NLP

3. Final Refraction at Last Post-op Visit for Operative Eye:

+ / - ___ ___ ___ ___ + / - ___ ___ ___ ___ x ___ ___ ___
circle sphere circle cyl axis

4. Number of Post-op Visits Through Day 120: _____

(indicate date of visit and type of provider [M.D. .O.D. or other])

Visit #1	Visit #2	Visit #3	Visit #4	Visit #5	Visit #6	Visit #7	Visit #8
/ /	/ /	/ /	/ /	/ /	/ /	/ /	/ /
mm/dd/yy	mm/dd/yy	mm/dd/yy	mm/dd/yy	mm/dd/yy	mm/dd/yy	mm/dd/yy	mm/dd/yy
☐ 1 M.D.	☐ 1 M.D.	☐ 1 M.D.	☐ 1 M.D.	☐ 1 M.D.	☐ 1 M.D.	☐ 1 M.D.	☐ 1 M.D.
☐ 2 O.D.	☐ 2 O.D.	☐ 2 O.D.	☐ 2 O.D.	☐ 2 O.D.	☐ 2 O.D.	☐ 2 O.D.	☐ 2 O.D.
☐ 3 Other	☐ 3 Other	☐ 3 Other	☐ 3 Other	☐ 3 Other	☐ 3 Other	☐ 3 Other	☐ 3 Other

5. If Best Corrected Distance Acuity < 20/25, Etiology *(for operative eye)*:

(check all that apply)

- ☐ 1 Amblyopia
- ☐ 2 Macular degeneration
- ☐ 3 Glaucoma
- ☐ 4 Diabetic retinopathy
- ☐ 5 Other retinal vascular disease
- ☐ 6 Macular edema
- ☐ 7 Posterior capsular opacification
- ☐ 8 Corneal edema
- ☐ 9 Other *(specify)* _____
- ☐ 0 Unknown

6. Nd: YAG Capsulotomy Within 120 Days After Surgery *(for operative eye)*:

Yes ☐ 1 If Yes. Date: ___/___/___
No ☐ 0 mm dd yy

Appendix B

National Study of Cataract Outcomes (Cataracts PORT)
Clinical Data Forms

National Study of Cataract Outcomes
Johns Hopkins University
1830 E. Monument Street, Room 8068
Baltimore, Maryland 21205

BASELINE
CLINICAL DATA FORM

Patient Name: _____

This form is to be used to provide <u>preoperative</u> clinical data about the patient named above who is scheduled for cataract surgery. It should be completed as soon as you are notified of the patient's enrollment in the study and before surgery is performed.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK."

When the form is completed, please remove this page and return the top copy to the National Study of Cataract Outcomes in the stamped addressed envelope provided. The second copy should be kept in your office.

NATIONAL STUDY OF CATARACT OUTCOMES

Baseline Clinical Data Form

1. OPHTHALMOLOGIC HISTORY

Does the patient have any eye disease other than cataract? ☐ YES ☐ NO (GO TO Q.2) EYEDISEA

IF YES: Does the patient have any of the following? *(Please check YES or NO for each item)*

YES	NO		YES	NO	
☐	☐	Amblyopia AMBLYOPI CHRONIC	☐	☐	Previous retinal detachment PREV_RD
☐	☐	Chronic external disease (e.g., blepharoconjunctivitis)	☐	☐	Diabetic retinopathy (any degree) DIAB_RET
☐	☐	Dry eye syndrome DRYEYE	☐	☐	Diabetic retinopathy with past laser treatment
☐	☐	Fuchs' Dystrophy FUCHS	☐	☐	Glaucoma or ocular hypertension (any degree)
☐	☐	Chronic uveitis or keratitis UVEITIS	☐	☐	Glaucoma with central field loss or previous laser or filte
☐	☐	Visually impairing age-related macular degeneration (ARMD) ARMD	☐	☐	Other optic nerve disease OPTIC_NE
			☐	☐	History of prior intraocular surgery PRIOR_

2. MEDICAL HISTORY AT BASELINE

Does the patient have any known medical conditions? ☐ YES ☐ NO (GO TO Q.3) MEDICAL

IF YES: Does the patient have any of the following? *(Please check YES or NO for each item)*

YES	NO		YES	NO	
☐	☐	Type-I diabetes (juvenile or ketoacidosis prone) TYPE1_DI	☐	☐	Chronic renal disease RENAL
☐	☐	Type-II diabetes (adult, not ketoacidosis prone) TYPE2_DI	☐	☐	Neoplasm NEOPLASM
X	☐	☐ Hypertension HYPERTEN	☐	☐	Chronic steroid therapy STEROID
☐	☐	Angina ANGINA	☐	☐	Inflammatory bowel disease BOWEL
☐	☐	Past myocardial infarction MI	☐	☐	Rheumatoid or collagen vascular disease RHEUMATI
☐	☐	Past stroke STROKE	☐	☐	Altered mental status MENTAL
☐	☐	Asthma, COPD, or bronchitis ASTHMA			

3. BEST CORRECTED DISTANCE ACUITY

(Choices: 20/20 - 20/400, CF6, CF3, CF1, HM, LP, NLP)

RIGHT 20/|_|_|_| VA_RR(decimal) LEFT 20/|_|_|_| VA_LL(decima

4. REFRACTION

		CIRCLE	SPHERE	SIGN	CYL	AXIS
RIGHT EYE	+/-	CIRCLE_R	SPHERE_R	SIGN_R	CYL_R	AXIS_R
		|_|.|_|_|	+ |_|.|_|_|		x |_|_|_|	
LEFT EYE	+/-	CIRCLE_L	SPHERE_L	SIGN_L	CYL_L	AXIS_L
		|_|.|_|_|	+ |_|.|_|_|		x |_|_|_|	

5. KERATOMETRY IN DIOPTERS (In operated eye)

KERA_D_1 |_|_|.|_|_| D @ KERA_M_1 |_|_|_|° , KERA_D_2 |_|_|.|_|_| D @ KERA_M_2 |_|_|_|°

6. AXIAL LENGTH (In operated eye)

AXIAL_LE |_|_|.|_|_| mm

7. INTRAOCULAR PRESSURE (applanation)

IOP_R RIGHT |_|_| mm IOP_L LEFT |_|_| mm

8. PUPILS

	RIGHT	LEFT	
PUPIL_R	☐	☐	Normally reactive
	☐	☐	Afferent defect
PUPIL_L	☐	☐	Cannot assess

9. CONJUNCTIVA, CORNEA, AND SCLERA *(Check one for each eye)*

	RIGHT	LEFT	
CONJ_R	☐	☐	Normal
CONJ_L	☐	☐	Abnormal *(if abnormal)* →
	☐	☐	Cannot assess

	RIGHT	LEFT	*(Check all that apply)*
FILTER_R	☐	☐	Prior filtering surgery FILTER_L
GTATTA_R	☐	☐	Guttata (exceeding expected for age) GTATTA_L
EDEMA_R	☐	☐	Edema EDEMA_L
SCAR_R	☐	☐	Corneal scar reducing vision SCAR_L
GRAFT_R	☐	☐	Graft GRAFT_L
OTHER_R	☐	☐	Other corneal pathology OTHER_L

10. ANTERIOR CHAMBER FINDINGS *(Check one for each eye)*

	RIGHT	LEFT	
AC-R / AC-L	☐	☐	Normal
	☐	☐	Abnormal *(if abnormal)* →
	☐	☐	Cannot assess

UVETIS-R, PSTSYN-R, VITRES-R, CTH10-R

RIGHT	LEFT	*(Check all that apply)*
☐	☐	Active uveitis or iridocyclitis UVETIS-L
☐	☐	Posterior synechiae PSTSYN-L
☐	☐	Vitreous in AC VITRES-L
☐	☐	Other AC findings CTH10-L

11. LENS *(Check one for each eye)*

	RIGHT	LEFT	
	☐	☐	Normal
LNSNUM-R	☐	☐	Nuclear cataract
LNSNUM-L	☐	☐	Cortical cataract
	☐	☐	Posterior subcapsular cataract
	☐	☐	Other abnormality *(indicate)* →
	☐	☐	Cannot assess

LENSOTH-R, LENSOTH-L

NUCLAR-R NUCLAR-L
CORTCL-R CORTCL-L
PSC-R PSC-L

RIGHT	LEFT	*(Check all that apply)*
☐	☐	Hypermature cataract HYPER-R, HYPER-L
☐	☐	Congenital cataract CONGEN-R, CONGEN-L
☐	☐	Secondary cataract SECOND-R SECOND-L
☐	☐	Lens dislocation or subluxation DISLOC-R DISLOC-L

12. OPTIC NERVE *(Check one for each eye)*

	RIGHT	LEFT	
OPTIC-R / OPTIC-L	☐	☐	Normal
	☐	☐	Abnormal *(if abnormal)* →
	☐	☐	Cannot assess

CUPPNG-R, NEUROR-R, NGLAUC-R, OTH12-R

RIGHT	LEFT	*(Check all that apply)*
☐	☐	Glaucomatous atrophy (cupping) CUPPNG-L NEUROR-L
☐	☐	Non-glaucomatous atrophy NGLAUC-L
☐	☐	Other optic nerve findings OTH12-L

13. MACULA *(Check one for each eye)*

	RIGHT	LEFT	
MACULA-R / MACULA-L	☐	☐	Normal
	☐	☐	Abnormal *(if abnormal)* →
	☐	☐	Cannot assess

SCATR-R, CONFL-R, NGEOG-R, GEOG-R, NEOVS-R, DISC R, MACDMA-R, MACHLE-R, OTH13-R

RIGHT	LEFT	*(Check all that apply)*
☐	☐	Scattered drusen n SCATR-L
☐	☐	Confluent drusen y CONFL-L
☐	☐	Nongeographic (mottled) atrophy n NGEOG-L
☐	☐	Geographic atrophy y GEOG-L
☐	☐	Neovascular change or membrane y NEOVS-L
☐	☐	Disciform scar or hemorrhage y DISC-L Y=AMD
☐	☐	Macular edema n MACDMA-L
☐	☐	Macular hole/cyst n MACHLE-L
☐	☐	Other macular or RPE pathology n OTH13-L

14. RETINA *(Check one for each eye)*

	RIGHT	LEFT	
RETINA-R / RETINA-L	☐	☐	Normal
	☐	☐	Abnormal *(if abnormal)* →
	☐	☐	Cannot assess

DETCH-R, BDR-R, PPR-R, PDR-R, PRP-R, VITHEM-R, BRAO-R, BCRAO-R, BRVO-R, CRVO-R, RETDEG-R, OTH14-R

RIGHT	LEFT	*(Check all that apply)*
☐	☐	Retinal detachment n DETCH-L
☐	☐	Background diabetic retinopathy n BDR-L
☐	☐	Pre-proliferative retinopathy n PPR-L
☐	☐	Proliferative diabetic retinopathy n PDR-L
☐	☐	Panretinal photocoagulation (previous) n PRP-L
☐	☐	Vitreous hemorrhage n VITHEM-L
☐	☐	Branch retinal artery occlusion n BRAO-L
☐	☐	Central retinal artery occlusion n CRAO-L
☐	☐	Branch retinal vein occlusion n BRVO-L
☐	☐	Central retinal vein occlusion n CRVO-L
☐	☐	Retinal degen. (myopic, lattice, etc.) n RETDEG-L
☐	☐	Other retinal pathology n OTH14-L

15. **AMSLER GRID** *(Check one)*

RIGHT	LEFT	
AMSLR-R ☐	☐	Normal
AMSLR-L ☐	☐	Distorted
☐	☐	Not performed

16. **GLARE TESTING** (# Snellen lines decrease) *(Check one)*

RIGHT	LEFT	
GLARE-R ☐	☐	0 Lines
☐	☐	1 Line
GLARE-L ☐	☐	2 Lines
☐	☐	3 Lines
☐	☐	4 Lines or more
☐	☐	Not performed

If performed, specific instrument used: GLARETEC - INSTRUMT

LIGHT INTENSITY: ☐ Low ☐ Medium ☐ High INTENS

17 **TESTING FOR POTENTIAL ACUITY** *(Answer one)* NOPREDVA

1. Predicted Acuity PRDVA-R RIGHT 20/|_|_|_|
   (PRDVA-L) (examinator) LEFT 20/|_|_|_|
2. Not Performed _____ ☐

If performed, specific instrument used:
- ☐ PAM PREDINCT
- ☐ Interferometer
- ☐ Other _____

18. **EYE SCHEDULED FOR CATARACT SURGERY FIRST** *(Check one)* EYECDF ☐ RIGHT ☐ LEFT

19. **TYPE OF SURGERY PLANNED** *(Check one)* TYPE-SUR

- ☐ Extracapsular (manual expression of nucleus)
- ☐ Extracapsular (phacoemulsification)
- ☐ Endocapsular aspiration
- ☐ Endocapsular phacoemulsification
- ☐ Intracapsular
- ☐ Other _____

20. **IOL PLANNED** *(Check one)* IOL

- ☐ Posterior chamber standard
- ☐ Posterior chamber foldable
- ☐ Anterior chamber
- ☐ Other _____
- ☐ None

21. **RISK ASSESSMENT**

Is there increased risk in this patient of: *(Please check YES or NO for each condition)*

YES	NO		YES	NO	
☐	☐	Chronic inflammation RISK-INF	☐	☐	Cystoid macular edema RISK-CME
☐	☐	Hemorrhage or hyphema RISK-HEM	☐	☐	Transient IOP increase RISK-ICP
☐	☐	Zonular or capsular rupture RISK-ZCN	☐	☐	Transient hypotony RISK-TRH
☐	☐	Vitreous loss or vitrectomy RISK-VIT	☐	☐	Sustained glaucoma RISK-GLA
☐	☐	Retinal break/retinal detachment RISK-RD	☐	☐	Sustained hypotony RISK-SUH
☐	☐	Corneal edema RISK-CE	☐	☐	Other RISK-OTH RISK-SP1

IF YES TO ANY OF THE ABOVE, EXPLAIN BELOW:

RISK-EX1

22. **EXPECTED POSTOPERATIVE ACUITY IN OPERATED EYE** *(Check one)*

- ☐ 20/15 - 20/30
- ☐ 20/40 - 20/50
- ☐ 20/60 - 20/80
- ☐ 20/100 - 20/200
- ☐ 20/400 or worse

EXPECT_V

IF 20/40 OR WORSE, EXPLAIN BELOW:

EXP_E1

23. **DATE FORM COMPLETED** DATE_COM **MONTH** |_|_| **DAY** |_|_| **YEAR** |_|_|

Thank you for completing this form.

Please mail the top copy of this form to the National Study of Cataract Outcomes in the stamped addressed envelope that has been provided.

Additional visual Acuity variables.

opva_va
nopva_va

bcdva
wcdva

cpvaqp1
bcdvaqp1

logmar
logmar

logmar
logmar

avgeye
avgmar
wavgmar

prdva_rr
prdva_ll

National Study of Cataract Outcomes
Johns Hopkins University
1830 E. Monument Street, Room 8068
Baltimore, Maryland 21205

PERIOPERATIVE CLINICAL DATA FORM

Patient Name: _____

This form should be completed within 24 hours following surgery, preferably at a followup visit on Day 1 postop.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK."

When the form is completed, please remove this page and return the top copy to the National Study of Cataract Outcomes in the stamped addressed envelope provided. The second copy should be kept in your office.

NATIONAL STUDY OF CATARACT OUTCOMES

Perioperative Clinical Data Form

SURGICAL APPROACH

1. **OPERATED EYE** (DATE OF SURGERY: |_|_| - |_|_| - |_|_|_|) DATESURG
MONTH DAY YEAR
☐ RIGHT ☐ LEFT
OPEYE

2. **TYPE OF CATARACT EXTRACTION** *(Check one)*

TYPEEXTR

- ☐ Extracapsular (manual expression of nucleus)
- ☐ Extracapsular (phacoemulsification)
- ☐ Converted (Phacoemulsification converted to standard extracapsular technique)
- ☐ Endocapsular phacoemulsification
- ☐ Endocapsular aspiration
- ☑ Intracapsular

3. **TYPE OF ANESTHESIA** *(Check one)*

TYPEANES

- ☐ General
- ☐ Retrobulbar block
- ☐ Peribulbar block

If retrobulbar or peribulbar: *(Check one in each box)*

(Check one)
- ☐ Patient monitored by anesthesiologist PATMON
- ☐ Patient monitored by anesthetist
- ☐ Patient monitored by someone else *(Specify)* MONOTHER

(Check one)
- ☐ Block administered by surgeon BLOCKADM
- ☐ Block administered by anesthesiologist
- ☐ Block administered by anesthetist
- ☐ Block administered by someone else *(Specify)* ADMOTHER

4. **INCISION LENGTH** |_|_| mm INCISION

5. **TYPE OF CAPSULOTOMY** *(Check one)* TYPECAPS

- ☐ Can opener with cystotome/needle
- ☐ Scissors capsulotomy
- ☐ Continuous tear capsulotomy

6. **INTRAOCULAR LENS** *(Check one)*

- Manufacturer IOLMANUF
- Model # IOLMODEL
- Optic Size IOLSIZE

(Check one) IOLTYPE reasonable to say all either

- ☐ Standard posterior chamber in bag
- ☐ Standard posterior chamber in sulcus
- ☐ Foldable posterior chamber
- ☐ Anterior chamber
- ☐ Planned suturing of posterior chamber lens
- ☐ Unplanned suturing of posterior chamber lens
- ☐ IOL planned but not implanted
- ☐ No IOL planned

7. **TYPE OF IRIDECTOMY** *(Check one)* TYPEIRID

- ☐ Peripheral iridotomy
- ☐ Peripheral iridectomy
- ☐ Sector
- ☐ None

8. **INTRAOPERATIVE POSTERIOR CAPSULOTOMY?** *(Check one)*

- ☐ Yes RETCAPS
- ☐ No

INTRAOPERATIVE AND POSTOPERATIVE COURSE

9. INTRAOPERATIVE EVENTS

Did the patient have any of the following? *(Please check YES or NO for each item)*

YES	NO		YES	NO	
☐	☑	Globe perforation during anesthesia GLOBPERF	☐	☑	Posterior capsular or zonular rupture POSRUP
☐	☑	Retrobulbar hemorrhage RETROHEM	☐	☑	Vitreous loss/anterior vitrectomy or aspiration VIT
☐	☐	Other anesthesia related complication ANESCOMP	☐	☑	Loss of nuclear fragment into vitreous LOSSNUCL
☐	☑	Anterior chamber hemorrhage ACHEM	☐	☐	Loss of IOL into vitreous LOSSIOL
☐	☐	Iridodialysis, cyclodialysis or iris trauma IRISTRAU	☐	☐	Choroidal hemorrhage CHORHEM
☐	☐	Persistent iris prolapse IRISPROL	☐	☐	Asymetric lens placement ASYMLENS
☐	☐	Incomplete cortical cleanup INCCORT	☐	☐	Abnormality in wound closure ABNWOUN
☐	☐	Residual posterior capsule opacity RESIDOPA			

10. POSTOPERATIVE EVENTS (Within 48 hours following surgery)

Does the patient have any of the following? *(Please check YES or NO for each item)*

YES	NO		YES	NO	
☐	☑	Endophthalmitis ENDOPH	☐	☑	Cystoid macular edema CME
☐	☑	Wound Leak or rupture WOUNDLEA	☐	☑	Retinal detachment RETDET
☐	☐	Hyphema HYPHEMA	☐	☑	Retinal tear or break (no detachment) RETTEAR
☐	☐	Posterior capsule opacification PCOPACI	☐	☑	Intraocular pressure greater than 30mm Hg: pupillary block IOPBOPUP
☐	☑	IOL dislocation IOLDISLO	☐	☐	Intraocular pressure greater than 30mm Hg: nonpupillary block IOPBONP
☐	☐	Retained lens material RETNLENS	☐	☑	Optic neuropathy OPTICNEU
☐	☐	Inflammation greater than expected INFLAMM	☐	☐	Other complication *(Specify)* OTHERCOM
☐	☐	Iris abnormalities (atrophy, etc.) IRISABN			
☐	☑	Corneal edema CORNEDEM			

11. IS SURGERY PLANNED FOR SECOND EYE?

☐ No SUREPLAN ☐ Yes, planned for (DATE: |_|_| - |_|_| - |_|_|) SURG2DAT
MONTH DAY YEAR

IMPORTANT: IF CATARACT SURGERY IS SCHEDULED FOR THE SECOND EYE WITHIN 4 MONTHS OF THE FIRST SURGERY, PLEASE NOTIFY THE INTERVIEWER ASSIGNED TO YOUR OFFICE.

12. DATE FORM COMPLETED DATECOMP

MONTH |_|_| DAY |_|_| YEAR |_|_|

Thank you for completing this form.

Please mail the top copy of this form to the National Study of Cataract Outcomes in the stamped addressed envelope that has been provided.

National Study of Cataract Outcomes
Johns Hopkins University
1830 E. Monument Street, Room 8068
Baltimore, Maryland 21205

4-MONTH FOLLOWUP CLINICAL DATA FORM

Patient Name: _____

This form should be completed approximately 4 months after surgery.

Please answer all questions on the form. If you do not know the answer to a particular question please write in "DK."

When the form is completed, please remove this page and return the top copy to the National Study of Cataract Outcomes in the stamped addressed envelope provided. The second copy should be kept in your office.

NATIONAL STUDY OF CATARACT OUTCOMES

4-Month Followup Clinical Data Form

OUTCOME OF CATARACT SURGERY
Day 0 - Day 120 (First 4 Months)

1. POSTOPERATIVE EVENTS *(Check YES or NO)*

IF YES: *Give date*

	YES	NO		MONTH	DAY	YEAR
m4endoph	☐	☐	✓ Endophthalmitis	ENDO_DAT		
m4woleak	☐	☐	✓ Wound Leak or rupture	WOUND_DAT		
m4hyphem	☐	☐	Hyphema	HYPH_DAT		
m4pcapac	☐	☐	✓ Posterior capsule opacification	PCC_DATE		
m4iolds	☐	☐	✓ IOL dislocation	IOLD_DAT		
m4iolrem	☐	☐	IOL removal or exchange	IOLR_DAT		
m4retlen	☐	☐	Retained lens material	RETN_DAT		
m4inflam	☐	☐	Inflammation greater than expected	INFL_DAT		
m4irisab	☐	☐	Iris abnormalities (synechiae, etc.)	IRIS_DAT		
m4corned	☐	☐	✓ Corneal edema greater than expected	CORN_DAT		

	YES	NO		MONTH	DAY	YEA
m4cme	☐	☐	✓ Cystoid macular edema	CME_DATE		
m4vitdet	☐	☐	Posterior vitreous detachment	VITR_DAT		
m4retdet	☐	☐	✓ Retinal detachment	RDDATE		
	☐	☐	✓ Retinal tear or break (no detachment)			
m4retear	☐	☐		RT_DATE		
m4iopsc	☐	☐	Intraocular pressure greater than 30mmHg	IOPSC_DA		
	☐	☐	Optic neuropathy	OPTIC_DA		
	☐	☐	Other complications *(Specify)*			

m4cpneur _____ OTHER_DA →

m4c_comp _____

2. SUTURES CUT? m4suture

☐ Yes

☐ No → Number of visits at which suture(s) were cut: m4numsct

3. ✓ POSTERIOR CAPSULOTOMY PERFORMED? m4pcperf

☐ Yes (DATE: |__|__|-|__|__|-|__|__|) MONTH DAY YEAR m4pc_date

☐ No → *If yes: (Check one)* m4pctype

☑ Nd: YAG

☐ Needle/knife

4. CATARACT SURGERY PLANNED IN SECOND EYE? m4sure2

☐ No

☐ Yes, planned for (DATE: |__|__|-|__|__|-|__|__|) m4s2date

☐ Already performed (DATE: |__|__|-|__|__|-|__|__|)

5. ✓ BEST CORRECTED DISTANCE ACUITY (SNELLEN) *(Choices: 20/20 - 20/400, CF6, CF3, CF1, HM, LP, NLP)*

RIGHT 20/|__|__|__| m4va_rr(decimal) LEFT 20/|__|__|__| m4va_ll(decima

6. ✓ REFRACTION (In operated eye) m4circ_c

+/- CIRCLE m4sph_c |__|.|__|__| SPHERE + m4cyl_c |__|.|__|__| CYL x m4axis_c |__|__|__| AXIS

m4sign_c

7. INTRAOCULAR PRESSURE (applanation) m4iop_r

RIGHT |__|__| mm m4iop_l LEFT |__|__| mm

8. KERATOMETRY IN DIOPTERS (In operated eye) m4kerm1

|__|__|.|__|__| D @ |__|__|° m4kerax1 |__|__|.|__|__| D @ m4kerax2 |__|__|° m4kerax2

9. CORNEAL EXAMINATION (In operated eye) *(Check all that apply)*

☐ Normal with secure wound and sutures - m4c_norm

☐ Wound gape m4c_gape

☐ Broken sutures or protruding ends m4c_brok

☐ Corneal edema m4c_ce

☐ Descemet's folds m4c_desc

☐ Descemet's tear or detachment m4c_tear

☐ Other abnormality - m4c_oth

m4c_spec

10. IRIS AND PUPIL (in operated eye) *(Check all that apply)*

- ☐ Normal with no iridectomy M4I-NNI
- ☐ Normal with surgical iridectomy M4I-NSI
- ☐ Nonreactive pupil M4I-NONR
- ☐ Ectatic pupil M4I-ECTP
- ☐ Iris atrophy (including phaco induced) M4I-ATRO
- ☐ Posterior synechia to capsule or IOL M4I-PC
- ☐ Anterior synechiae M4I-ASYN
- ☐ Afferent pupillary defect M4I-AFD
- ☐ Other abnormality M4I-OTH M4I-SPEC

11. ANTERIOR CHAMBER FINDINGS (in operated eye) *(Check all that apply)*

- ☐ Normal and uninflamed M4A-NORM
- ☐ Inflammation (cell and flare) M4A-FLAM
- ☐ Hypopyon M4A-HYPO
- ☐ Residual lens cortex M4A-RESL
- ☐ Hyphema M4A-HYPH
- ☐ Other abnormality M4A-OTH M4A-SPEC

12. LENS (in operated eye) *(Check all that apply)*

- ☐ Normally centered intraocular lens M4L-NORM
- ☐ IOL optic-pupil misalignment in undilated state M4L-[redacted]IDL
- ☐ Pupillary capture of IOL M4L-[redacted]PUPL
- ☐ Posterior displacement of PC IOL optic or haptic M4L-PIOL
- ☐ Posterior displacement of anterior chamber IOL or haptic M4L-AIOL
- ☐ Residual lens cortex M4L-RES
- ☐ Other abnormality M4L-OTH M4L-SPEC

13. OPTIC NERVE (in operated eye) *(Check all that apply)*

- ☐ Normal M4O-NORM
- ☐ Optic atrophy (pallor) M4O-ATRO
- ☐ Optic nerve hemorrhage M4O-NERV
- ☐ Glaucomatous atrophy M4O-GLAU
- ☐ Other abnormality M4O-OTH M4O-SPEC

14. MACULA (in operated eye) *(Check all that apply)*

- ☐ Normal M4M-NORM
- ☐ Angiographic cystoid edema M4M-ANGC
- ☐ Clinically significant cystoid edema M4M-CSCE
- ☐ ARMD M4M-ARMD
- ☐ Macular cyst or hole M4M-CYST
- ☐ Other abnormality M4M-OTH M4M-SPEC

15. RETINA *(Check all that apply)*

- ☐ Normal M4R-NORM
- ☐ Retinal detachment M4R-RD
- ☐ Retinal tear (non-detached) M4R-RT
- ☐ Retinal vascular occlusion M4R-RVO
- ☐ Other abnormality M4R-OTH M4R-SPEC

16. VISUAL ACUITY

✓ Is vision less than 20/25? ☐ YES ☐ NO (GO TO Q.17) M4VA20

IF YES: Is the etiology due to: *(Check YES or NO for each item)*

YES	NO		
✓ ☐	☐	ARMD	M4VAARMD
✓ ☐	☐	Cystoid macular edema	M4VACME
✓ ☐	☐	Posterior capsule opacification	M4VAPCO
✓ ☐	☐	Corneal edema	M4VACE
☐	☐	Lens decentration or dislocation	M4VALENS
☐	☐	Astigmatism	M4VASTIG
☐	☐	Other (Describe)	M4VAOTH M4VASP1

17. CHANGES IN FUNCTIONAL STATUS *(Check one)*

- ☐ Improved functional status
- ☐ No change in functional status M4FUNCST
- ☐ Worsened functional status (Describe) M4FUNC1

YES	NO	(Check YES or NO for each)
☐	☐	Improved activities of daily living M4IMADL
☐	☐	Improved reading ability M4IMREAD
☐	☐	Improved driving ability M4IMDRIV
☐	☐	Improved ambulation M4IMAMBU
☐	☐	Other improvements (Describe) M4IMOTH M4IMSP1

18. DATE FORM COMPLETED _____ MONTH |_|_| DAY |_|_| YEAR |_|_|

Thank you for completing this form.

Please mail the top copy of this form to the National Study of Cataract Outcomes in the [redacted] stamped addressed envelope that has been provided.

Appendix C

Construction of Comparable Variables from Demonstration and PORT Data Collection Instruments

Section 4.3 compares patients of demonstration providers at baseline to patients included in the PORT data base. This appendix shows how comparable variables were created from the two sources.

Variable of Interest	Checklist Source and Construction	PORT Source and Construction
Patient Age	Date of Birth Operative Date *(Age=Date of Surgery-Date of Birth)*	Age *(provided by physician, not recorded on the checklist)*
Pre-Operative Visual Acuity in Operative Eye	Best Corrected Pre-Operative Distance Acuity: Right (OD) 20/____ Left (OS) 20/____ CF, HM, LP, NLP	Best Corrected Distance Acuity: Right (OD) 20/___ Left (OS) 20/___ CF6, CF3, CF1, HM, LP, NLP
Type of Cataract	**Lens Condition**	**Lens**
Nuclear	Nuclear Cataract	Nuclear Cataract (Right, Left)
Cortical	Cortical Cataract	Cortical Cataract (Right, Left)
PSC	Posterior Subcapsular Cataract	Posterior Subcapsular Cataract (Right, Left)
Pre-Operative Pathologies		
No Ocular Disease Other than Cataract	No ocular disease other than cataract =*yes in 2a or no other pathologies indicated in 2a*	Does the patient have any eye disease other than cataract?=*no*
Amblyopia	Amblyopia (2a)	Amblyopia
Age-Related Macular Degeneration	Age-Related Macular Degeneration (2a)	Visually impairing age-related macular degeneration (ARMD)
Glaucoma	Glaucoma (2a)	*combine two items* 1. Glaucoma or ocular hypertension (any degree) 2. Glaucoma with central field loss or previous laser or filter
Other Optic Nerve Disease	Other optic nerve disease (2a)	Other optic nerve disease
Chronic Uveitis or Keratitis	Chronic uveitis or keratitis (2a)	Chronic uveitis or keratitis
Previous Retinal Detachment	Previous retinal detachment (2a)	Previous retinal detachment
Diabetic Retinopathy	Diabetic retinopathy (2a)	*combine two items:* 1. Diabetic retinopathy (any degree) 2. Diabetic retinopathy with past laser treatment
History of Prior Intraocular Surgery	History of prior intraocular surgery (2a)	History of prior intraocular surgery

Variable of Interest	Checklist Source and Construction	PORT Source and Construction
Cataract Extraction Technique	**Type of Surgery Performed**	**Type of Surgery Planned**
ECCE	Extracapsular with manual nuclear expression	Extracapsular (manual expression of nucleus)
phaco	*combine two items:* 1 Extracapsular with iris plane/anterior chamber phacoemulsification 2. Posterior chamber phacoemulsification	*combine two items:* 1. Extracapsular (phacoemulsification) 2.Endocapsular phacoemulsification
converted	Converted (phaco converted to manual extracap)	Converted (phaco converted to standard extracap. technique)
other/surgery aborted	*combine two items:* 1. Intracapsular 2. Other	*combine three items:* 1.Intracapsular 2. Endocapsular aspiration 3. Other
Type of IOL Implanted	**IOL Implanted**	**IOL Planned**
Posterior Chamber Standard	Posterior Chamber Standard	*combine two items:* 1.Standard Posterior Chamber in bag 2.Standard Posterior Chamber in Sulcus
Posterior Chamber Foldable	Posterior Chamber Foldable	Foldable Posterior Chamber
Anterior Chamber	Anterior Chamber	Anterior Chamber
Other	*combine two items:* 1. Suture Fixated IOL 2. Multifocal IOL	*combine two items:* 1. Planned suturing of posterior chamber lens 2. Unplanned suturing of posterior chamber lens
Capsulotomy Technique	**Type of Capsulotomy**	**Type of Capsulotomy**
Can Opener	Can Opener with cystotome/needle	Can Opener with cystotome/needle
Scissors	Scissors	Scissors Capsulotomy
Continuous Tear	Continuous Tear	Continuous Tear Capsulotomy
YAG Capsulotomy Within 120 Days After Surgery	Nd: YAG Capsulotomy Within 120 Days After Surgery	*combine two items:* 1. Posterior Capsulotomy Performed? 2. Nd:YAG

Variable of Interest	Checklist Source and Construction	PORT Source and Construction
Type of Intraoperative Event	**Significant Intraoperative Event**	**Intraoperative Events: Does patient have any of the following (Y/N)?**
No Intra-Operative Event/ Any Event	*Based on the 7 variables below*	*Based on the 7 variables below*
Posterior capsular/zonal rupture	Posterior capsular/zonal rupture	Posterior capsular or zonal rupture
Vitreous loss/ anterior vitrectomy	Vitreous loss/ anterior vitrectomy	Vitreous loss/ anterior vitrectomy or aspiration
Posterior loss of nuclear fragment	Posterior loss of nuclear fragment	Loss of nuclear fragment into vitreous
Choroidal hemorrhage	Choroidal hemorrhage	Choroidal hemorrhage
Retrobulbar hemorrhage	Retrobulbar hemorrhage	Retrobulbar hemorrhage
Globe perforation during anesthesia	Globe perforation during anesthesia	Globe perforation during anesthesia
Anterior chamber hemorrhage	Anterior chamber hemorrhage	Anterior chamber hemorrhage
Type of Post-Operative Event	**Post-Operative Events Occurring Between Surgery and Last Post-op Visit (Date) For Operative Eye:** **Present anytime between surgery and last post-op visit**	**Post-Operative Events** ***combine two items:*** ***1. post-op events within 48 hours following surgery (from peri-operative data form)*** ***2. post-operative events (from 4 month follow-up data form)***
No Post-Operative Event/ Any Event	*Based on the 4 variables below*	*Based on the 4 variables below*
Endolphthalmitis	Endolphthalmitis	Endolphthalmitis
IOL Dislocation	IOL Dislocation (pupil optic misalignment)	IOL dislocation
Wound Leak/rupture	Wound Leak/rupture	Wound Leak or rupture
Retinal Tear/Detachment	Retinal Tear/Detachment	*combine two items* 1. Retinal detachment 2. Retinal tear or break, no detachment
Post-Operative Visual Acuity in Operative Eye	Best Corrected Distance Vision at Last Post-op Visit: Right (OD) 20/____ Left (OS) 20/____ CF, HM, LP, NLP	Best Corrected Distance Acuity: Right (OD) 20/___ Left (OS) 20/___ CF6, CF3, CF1, HM, LP, NLP
Change in Snellen Lines	*Derived from visual acuity measures*	*Derived from visual acuity measures*

Appendix D

Multivariate Regressions

The regression analyses supplement the simple comparisons. They investigate whether there are statistically significant differences between the PORT and baseline patients or between baseline and demonstration patients controlling for pre-operative characteristics of the patients.

Regression analysis is performed for four outcomes measures:

- **intra-operative complications**- whether the patient had one or more of the following complications during surgery: posterior capsular/zonular rupture, vitreous loss, posterior loss of nuclear fragment, choroidal hemorrhage, retrobulbar hemorrhage, globe perforation, anterior hemorrhage.

- **post-operative complications**
  for the PORT/baseline comparison
  whether the patient had one or more of the following complications within 120 days of surgery: endophthalmitis, IOL dislocation, wound leak/rupture, retinal tear/detachment

  for the within-site baseline/demonstration comparison
  whether the patient had one or more of the following complications at any time between surgery and the last post-operative visit: endophthalmitis, IOL dislocation, wound leak/rupture, retinal tear/detachment, or had one of the following conditions at the last post-operative visit: elevated IOP, persistent iritis, cystoid macular edema, corneal edema

- **log of visual acuity**

- **change in Snellen lines**

Model

for baseline/PORT comparison:

$y=\beta X + b$

X pre-operative characteristics
b indicator for baseline

The coefficient on b is the average difference between patients at demonstration sites (at baseline) and PORT patients.

for demonstration/baseline comparison:

complications
$y=\beta X + s + t$

X pre-operative characterisitics
s indicators for sites 3 and 4
t indicator for demonstration time period

The coefficient on t is the estimated average demonstration effect across all sites.

visual acuity
$y=\beta X + s + s*t$

X pre-operative characterisitics
s indicators for sites 3 and 4
s*t vector of interaction terms between provider indicators (Sites 1, 3, and 4) and an indicator for demonstration time period

The coefficients on the interaction terms are the estimated site-specific demonstration effects.

Characteristics included in X

indicator for age>70-79
indicator for age 80 plus
indicator for pre-operative VA between 20/50 and 20/70
indicator for pre-operative VA between 20/80 and 20/100
indicator for pre-operative VA 20/200 and worse
indicator for significant pre-operative pathology

Regression Results

PORT and Baseline Checklists

Outcome Measure	Any Intra-operative Event y/n			Any Post-operative Event y/n			Log of Post-operative Visual Acuity in Operative Eye		Change in Snellen Lines in Operative Eye	
method of estimation	*logit*			*logit*			*ordinary least squares*		*ordinary least squares*	
	beta	std error	odds ratio	beta	std error	odds ratio	beta	std error	beta	std error
intercept	-2.86***	0.67	.	-4.80***	1.31	.	-0.26***	0.07	1.72***	0.26
age 70-79	0.33	0.47	1.39	0.41	0.80	1.50	-0.16***	0.04	-0.66***	0.17
age >=80	-0.19	0.59	0.83	0.40	0.93	1.49	-0.34***	0.05	-1.39***	0.19
va 20/50-20/70	-0.07	0.52	0.93	0.65	1.07	1.92	-0.05	0.05	1.86***	0.19
va 20/80-20/100	-0.64	0.74	0.53	1.03	1.17	2.81	-0.12**	0.06	4.12***	0.24
va <=20/200	-0.05	0.61	0.95	-0.36	1.43	0.70	-0.57***	0.06	6.18***	0.23
no eye disease	-0.66*	0.36	0.52	-0.05	0.61	0.95	0.35***	0.04	1.19***	0.14
demo prov (baseline)	-0.54	0.38	0.58	-1.56**	0.78	0.21	-0.12***	0.03	-0.41***	0.13
N=1110	Chi Sq (7)=8.52			Chi Sq (7)=8.06			R Sq =.23		R Sq = .48	

*, **, *** indicate parameter estimates that are statistically significantly different than zero at the 90 percent, 95 percent, and 99 percent confidence levels respectively.
Sources: Cataract Surgery Alternate Payment Demonstration baseline checklists, 1221-1222; Cataract Patient Outcomes Research Team (PORT) data, 1991

Baseline and Demonstration Checklists

Outcome Measure	Any Intra-operative Event y/n			Any Post-operative Event y/n			Log of Post-operative Visual Acuity in Operative Eye		Change in Snellen Lines in Operative Eye	
method of estimation	*logit*			*logit*			*ordinary least squares*		*ordinary least squares*	
	beta	std error	odds ratio	beta	std error	odds ratio	beta	std error	beta	std error
intercept	-5.59***	0.66	.	-5.67***	0.55	.	-.39***	0.06	1.49***	0.22
age 70-79	0.10	0.28	1.11	0.18	0.17	1.20	-.09***	0.02	-.38***	0.09
age >=80	0.29	0.30	1.34	0.03	0.20	1.03	-.25***	0.03	-.94***	0.10
va 20/50-20/70	1.10**	0.48	3.00	0.10	0.23	1.10	-.05**	0.02	1.77***	0.09
va 20/80-20/100	1.33***	0.52	3.79	0.31	0.26	1.37	-.21***	0.03	3.68***	0.12
va <=20/200	1.15**	0.52	3.17	0.33	0.27	1.39	-.67***	0.03	5.86***	0.12
no eye disease	-0.22	0.21	0.80	-0.07	0.14	0.93	.35***	0.02	1.26***	0.07
site 3	inc	inc	inc	inc	inc	inc	0.08	0.07	0.00	0.25
site 4	inc	inc	inc	inc	inc	inc	-.11*	0.06	-.81***	0.24
time=demo	0.34	0.32	1.40	0.31	0.21	1.37	not inc	not inc	not inc	not inc
site 1*t=demo	not inc	not inc	not inc	not inc	not inc	not inc	0.02	0.05	-0.09	0.20
site 3*t=demo	not inc	not inc	not inc	not inc	not inc	not inc	0.04	0.05	-0.11	0.17
site 4*t=demo	not inc	not inc	not inc	not inc	not inc	not inc	.12***	0.04	.43***	0.16
	N=4097 Chi Sq (9)=71.95			N=4097 Chi Sq(9)=240.05			N=4077 R Sq=.22		N=4077 R Sq=.45	

*, **, *** indicate parameter estimates that are statistically significantly different than zero at the 90 percent, 95 percent, and 99 percent confidence levels respectively.
Sources: Cataract Surgery Alternate Payment Demonstration baseline and demonstration checklists, 1991-1996

CMS LIBRARY
3 8095 00012933 4